

Exhibit B

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4

5 * * * * *

6 IN RE: ETHICON, INC. * Master file No.
7 PELVIC REPAIR SYSTEM * 2:12-MD-02327
8 PRODUCTS LIABILITY * MDL NO. 2327
9 LITIGATION * JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

10 * * * * *

11 THIS DOCUMENT RELATES TO PLAINTIFFS:

12 Toni Hernandez
2:12-cv-02073

13
Karen Doucette

14 2:12-cv-02125
15 Sheryl & Kevin E. Lary
2:12-cv-02136

16
Teresa Scott
17 2:12-cv-02100

18 DEPOSITION OF PETER L. ROSENBLATT, M.D.

GYNEMESH PS
19 COURTYARD BY MARRIOTT
20 777 Memorial Drive
21 Cambridge, Massachusetts
22 July 1, 2016 9:00 a.m.

23
24 Maryellen Coughlin, RPR/CRR
25

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<p>1 APPEARANCES:</p> <p>2 Representing the Plaintiffs:</p> <p>3 MOSTYN LAW</p> <p>4 3810 W. Alabama Street</p> <p>5 Houston, Texas 77027</p> <p>6 BY: Jeff D. Crawford, Esq.</p> <p>7 713-714-0000</p> <p>8 Jeff@mostynlaw.com</p> <p>9 Representing the Defendants:</p> <p>10 BUTLER SNOW LLP</p> <p>11 1010 Highland Colony Parkway</p> <p>12 Ridgeland, Mississippi 39157</p> <p>13 BY: Paul S. Rosenblatt, Esq.</p> <p>14 601-985-4596</p> <p>15 paul.rosenblatt@butlersnow.com</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 EXHIBITS CONTINUED</p> <p>2 NO. DESCRIPTION PAGE</p> <p>3 9 "Current Controversies Regarding 189</p> <p>4 Oncologic Risk Associated with</p> <p>5 Polypropylene Midurethral</p> <p>6 Slings" by King, et al</p> <p>7 10 "Polypropylene as a 191</p> <p>8 reinforcement in pelvic surgery</p> <p>9 is not inert: comparative</p> <p>10 analysis of 100 explants" by</p> <p>11 Clavé</p> <p>12 11 "Long-Term Results of Burch 192</p> <p>13 Colposuspension" by Demirci</p> <p>14 12 "Biocompatibility of prosthetic 193</p> <p>15 meshes in abdominal surgery" by</p> <p>16 Binnebösel</p> <p>17 13 "Does the tension-free vaginal 194</p> <p>18 tape stay where you put it?" by</p> <p>19 Dietz</p> <p>20 14 "Ultrasound Assessment of 195</p> <p>21 Mid-Urethra Tape at Three-Year</p> <p>22 Follow-Up after Tension-Free</p> <p>23 Vaginal Tape Procedure" by Lo,</p> <p>24 et al</p> <p>25</p>
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P R O C E E D I N G S

PETER L. ROSENBLATT, M.D.,
having been first duly sworn, was examined
and testified as follows:

E X A M I N A T I O N

BY MR. CRAWFORD:

Q. Good morning, Doctor. My name is
Jeff Crawford, and I'm here this morning to ask
you some questions about the opinions you have
rendered in this case.

Do you understand that?

A. Yes.

Q. Would you state your full name for
the record, please?

A. Peter Rosenblatt.

Q. How would you describe your role in
this case?

A. I am -- I was asked by counsel to
render my opinion about various aspects of mesh
in the cases that were involved here.

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(Whereupon, Deposition Exhibit 1,
General Prolene, Gynemesh PS and Prolift
Expert report of Peter Rosenblatt, M.D.,
was marked for identification.)

BY MR. CRAWFORD:

Q. Okay. Do you recognize the
document that's been marked as Exhibit No. 1?

A. So this a little bit different
format than when I presented it, but it looks
like this is my general report.

Q. What do you mean a different format
than when you presented it?

A. I think when I --

MR. ROSENBLATT: I'll just
represent we added the cover page with the case
style to it.

A. Yeah. And, actually, when I sent
it, I think it was maybe a different font or
different size font, but this is my report.

Q. So originally you drafted an expert
report, a general causation expert report, and
you submitted it to someone?

A. I -- right, I did a report, and I
sent it in a Word format. I think maybe like the
reason that I took a minute is because I'm not

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sure it was doubled spaced the way it is. So it
just looked a little bit different than when I
sent it in, but this is the report.

Q. Who did you send it to?

A. I sent it to counsel.

Q. What counsel?

A. Mr. Rosenblatt.

Q. And Mr. Rosenblatt's with what
firm?

A. With Butler Snow.

Q. Representing Ethicon?

A. Representing Ethicon.

MR. ROSENBLATT: And, Jeff, I'll
state on the record, I don't know if you're going
to ask, there's no familial connection.

MR. CRAWFORD: That's interesting
to know.

Where's the original that you
submitted to defense counsel?

MR. ROSENBLATT: And I will just
object that under Rule 26 drafts are not
discoverable.

THE WITNESS: Can I answer or?

MR. ROSENBLATT: I mean, if it's on
your computer, you can say it's on your computer.

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A. It's on my computer.

Q. The one that's in front of you
right now as Exhibit No. 1, have you ever seen it
in that form, specifically in that font and
format?

A. Yes, I have. Just different than
the Word format that I sent. But I just -- when
you asked me, I wanted to make sure that this was
my report, and I've gone through it, and this is
my report.

Q. Does that document, Exhibit No. 1,
contain all the opinions that you hold in this
case?

A. You know, I'm happy to answer any
questions that you have if there are additional,
but I tried to put into the report all my
opinions, but if there are others that you want
to ask about today, I'm happy to answer that.

Q. Sure. But when you drafted
Exhibit No. 1, it was your intention to include
in that document all the opinions that you hold
in this case?

A. Yeah, I did the best I could with
respect to that.

Q. Since you've written it, between

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1 that time and today, are there any opinions that
 2 you've -- that you've come up with that aren't in
 3 that report?
 4 A. Not that I can think of.
 5 Q. When were you retained by Ethicon?
 6 A. I was not retained by Ethicon. I
 7 have had no discussions with Ethicon. I was
 8 asked by Attorney Rosenblatt and his firm to
 9 review the materials I think back maybe in March
 10 or April of this year.
 11 Q. Approximately March or April of
 12 2016 is when you were first approached or
 13 contacted by an attorney with Butler Snow about
 14 becoming involved in this case?
 15 A. Yeah, if I remember correctly, I
 16 think that actually Attorney Rosenblatt contacted
 17 me sometime in 2015, but then nothing happened at
 18 that point, and it was only when I was contacted
 19 earlier this year when, you know, I started to
 20 review materials.
 21 Q. When did you start to review
 22 materials?
 23 A. I think it was about March or
 24 April.
 25 Q. Had you ever done any work for or

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1 work with or for Butler Snow prior to being
 2 contacted in regards to this Ethicon case?
 3 A. No.
 4 Q. We are here today to talk to you
 5 about your general causation report, right?
 6 A. Yes.
 7 Q. To be clear, you have generated a
 8 general causation report about mesh in general,
 9 and then you've also been retained as an expert
 10 witness on specific cases; is that fair?
 11 A. Yes.
 12 Q. How many specific cases are you
 13 also retained for?
 14 A. I believe it was -- I believe it
 15 was five cases.
 16 Q. Do you know the names of them off
 17 the top of your head?
 18 A. Yeah, I remember there's Hernandez,
 19 Lary, L-A-R-Y, Loomis. I can't think of the
 20 others right now.
 21 Q. Are those approximately --
 22 A. Ah, Doucette is another one,
 23 D-O-U-C-E-T-T-E. Yeah.
 24 Q. Okay.
 25 A. And I think there's one more.

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1 Q. Are those approximately five cases
 2 that you're involved in now the only Ethicon
 3 transvaginal mesh cases you've ever been involved
 4 with?
 5 A. In terms of reviewing for the
 6 purposes of --
 7 Q. Yes, sir.
 8 A. -- this litigation.
 9 Q. Yes, sir.
 10 A. Yes. No, I think there was
 11 actually one other. One other, and I don't
 12 remember the name of that one, but apparently,
 13 that's for some reason not going forward.
 14 Q. There's a difference between
 15 reviewing cases and writing reports on cases,
 16 correct?
 17 A. I suppose so, but I don't know what
 18 the difference is.
 19 Q. Well, some of them you review and
 20 send back and then others you review and actually
 21 write a report and submit a report on, right?
 22 MR. ROSENBLATT: Object to form.
 23 A. So of the four or five, whatever it
 24 was that were sent to me, I reviewed the cases
 25 and wrote reports on each of the ones that I was

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1 asked to report on.
 2 Q. Okay. Have you been -- have any of
 3 the cases been submitted to you by Butler Snow
 4 that you didn't write reports on?
 5 A. There was -- you know, I was sent,
 6 and actually, it's probably in these boxes.
 7 There was I think one other that was sent to me
 8 but within a day I received a message that one of
 9 the cases I did not need to even look at, so I
 10 never actually, you know, looked at that case.
 11 Q. And who did that message come from?
 12 A. Someone at Butler Snow. I don't
 13 know if it was Attorney Rosenblatt or someone
 14 that he works with.
 15 MR. ROSENBLATT: And, Jeff, I will
 16 represent, if I remember correctly, I think it
 17 was a case that was either dismissed or -- it
 18 went away.
 19 Q. What did you do specifically to
 20 prepare for this general causation deposition?
 21 A. In addition to reviewing the
 22 records that were sent to me and writing the
 23 report and, you know, reviewing some of the
 24 literature, re-reviewing some of the literature,
 25 and reading through some of the other records

<p style="text-align: right;">Page 14</p> <p>1 that I had in terms of the IFUs and some internal 2 e-mails within Ethicon, that's general -- and 3 discussions with Attorney Rosenblatt. 4 Q. I'm particularly interested in the 5 literature that you re-reviewed just prior to 6 coming to your deposition. 7 Can you identify that literature 8 for me, please? 9 MR. ROSENBLATT: Object to form. 10 A. I would have a tough time 11 mentioning which ones because I just -- you know, 12 my mind doesn't work that way. But I looked at 13 some of the RCTs for both, you know, Prolift and 14 Gynemesh, and I re-reviewed the, you know, 15 Cochrane review and systematic reviews. 16 Q. Do you know what systematic 17 reviews? 18 A. The one I remember was the SGS 19 systematic review from several years ago. 20 Q. So as I understand it, as a general 21 causation expert in this case, you've reviewed a 22 lot of literature, fair to say? 23 A. Well, right. I mean, I've reviewed 24 it in connection with this, but I've also -- I've 25 known this literature from when it was published.</p>	<p style="text-align: right;">Page 16</p> <p>1 large retrospective studies. 2 Q. Is there a Category III? Is there 3 a Level III category of evidence in your mind? 4 A. Yes. 5 Q. What does that consist of? 6 A. You know, either, either case 7 reports or opinions, expert opinions. 8 Q. Would that include the expert 9 opinion of Dr. Rosenzweig? 10 A. Well, I've read -- I've read 11 Dr. Rosenzweig's -- I'm trying to remember what 12 I've read from him. I know I've read an expert 13 report in connection with this case, you know, 14 one of the cases, and I don't remember if I read 15 anything in the medical literature from 16 Rosenzweig specifically in connection with the 17 mesh literature. 18 (Whereupon, Deposition Exhibit 2, 19 Rule 26 Expert Report of 20 Bruce Rosenzweig, M.D., 21 was marked for identification.) 22 BY MR. CRAWFORD: 23 Q. I'm going to hand you what's marked 24 as Exhibit No. 2 to your deposition. Do you 25 recognize that document?</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Right. And of all of the 2 literature that you've reviewed over the years 3 concerning transvaginal mesh, you chose to review 4 three particular pieces of literature in 5 preparation for this deposition; is that fair? 6 MR. ROSENBLATT: Object to form. 7 Mischaracterizes the testimony. 8 A. Right, what I felt was most 9 important was to review what I thought was the 10 most important Level I evidence. 11 Q. And what is in your opinion the 12 most important Level I evidence in this case? 13 A. Well, that would be -- you know, 14 the Level I evidence was what I just mentioned, 15 systematic reviews, the Cochrane meta-analysis 16 and RCTs. 17 Q. Is there a group of evidence that 18 you categorize yourself as Level II evidence in 19 this case? 20 A. Yes. 21 Q. What is Level II evidence? What is 22 the Level II evidence comprised of? 23 A. I wouldn't be able to name it off 24 the top of my head but, you know, non-randomized 25 studies, so prospective cohort studies and some</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Yes. 2 Q. What is that? 3 A. This is Dr. Rosenzweig's expert 4 report. 5 Q. Is that his general causation 6 report? 7 MR. ROSENBLATT: For TVT? 8 A. Can you show me where this says 9 exactly what it is about? I'm happy to read it 10 all, if you want. 11 Q. If you'll just peruse it briefly 12 and tell me how you would describe that report. 13 It doesn't appear to be specific to any one 14 particular case, does it? 15 A. It does not. It appears to be 16 about TVT. 17 Q. Did you review Exhibit No. 2 in 18 preparation for this deposition? 19 A. I remember seeing a report by 20 Rosenzweig. I assume that this is it. I can't 21 say for certain, but I did see -- and if this is 22 the one that I reviewed, then I did. I didn't 23 review it specifically for this deposition, but 24 I've read through a lot of reports in the last 25 three months, and I believe this is one of them.</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. When was the first last time that 2 you reviewed a Rosenzweig report? 3 A. It's got to be over a month ago. 4 Probably more like two months ago. 5 Q. There's reference to literature in 6 his report, correct? 7 A. There appears to be, yes. 8 Q. When you reviewed Dr. Rosenzweig's 9 report, did you pull any of the literature that's 10 cited or referenced in that report? 11 A. Can you tell me which ones you're 12 referring to? 13 Q. Any of it. 14 A. Oh. 15 Q. For example, do you recall when 16 reviewing Dr. Rosenzweig's report reading any 17 footnotes or anything contained in that report 18 and looking up the literature that's referenced 19 therein? 20 MR. ROSENBLATT: And I'll just 21 represent he was not retained to offer opinions 22 on TVT. 23 A. So I don't recall specifically, but 24 I'm happy -- you know, if there is a reference 25 you want me to tell you -- you know, if you want</p>	<p style="text-align: right;">Page 20</p> <p>1 seen. 2 Q. Are there types of evidence that 3 you consider Level IV evidence? 4 A. If you could tell me what Level IV 5 is. I don't recall. 6 Q. I don't know. I was asking you. 7 Do you know -- 8 A. I can't remember if there is a 9 Level IV evidence. Yeah, for example, No. 11, 10 Clavé, I've read through that as well. 11 Q. In addition to what you've 12 identified as Level I, Level II and Level III 13 evidence, you've also reviewed internal e-mails 14 in preparation for this deposition, correct? 15 A. Well, I have read through them but, 16 you know, not specifically for this, in 17 preparation for this. I read them before I wrote 18 my report. Probably the last time I read through 19 internal documents was maybe, you know, four 20 weeks ago. 21 Q. Do any particular internal e-mails 22 that you reviewed approximately four weeks ago 23 come to mind? 24 A. Not specifically. 25 Q. There's an attorney sitting to your</p>
<p style="text-align: right;">Page 19</p> <p>1 to point to a reference, then I'll be happy to 2 tell you if I read that. But did I go through 3 his reference list and look all these articles 4 up, no. 5 Q. Yes, sir, that's what I was asking. 6 A. No, I couldn't do that. Time did 7 not permit it. 8 Q. Do you recall looking any of them 9 up? 10 A. No, I guess what I'm saying is that 11 there are -- oh, here we go. It's here at the 12 bottom. 13 MR. ROSENBLATT: I think it's 14 mostly company testimony, but he might have -- 15 THE WITNESS: That's what it looks 16 like. 17 MR. ROSENBLATT: -- a couple 18 literature references in there. 19 A. So that is correct. So I have no 20 idea about these company references. Like, for 21 instance, Reference 246 is an article from 22 de Tayrac in 2004, you know, that I've seen. And 23 there is another reference -- it actually doesn't 24 have a number by Jacquetin that I have seen, and 25 some of these reference videos which I have not</p>	<p style="text-align: right;">Page 21</p> <p>1 left, correct? 2 A. Yes. 3 Q. He's from Butler Snow? 4 A. Yes. 5 Q. Did you have an opportunity to meet 6 with him prior to this deposition? 7 A. I did. 8 Q. Where did that meeting take place? 9 A. We met for the last hour and a 10 half, two hours in the hotel. 11 Q. Your deposition is being taken in a 12 hotel? 13 A. Yes. 14 Q. In Cambridge, Massachusetts? 15 A. Yes. 16 Q. And for approximately an hour and a 17 half or so you were able to meet with defense 18 counsel prior to walking into this conference 19 room? 20 A. Correct. 21 Q. Did you take any notes during that 22 meeting? 23 A. No. 24 25</p>

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1 (Whereupon, Deposition Exhibit 3,
 2 Notice to Take Deposition of
 3 Dr. Peter Rosenblatt,
 4 was marked for identification.)
 5 BY MR. CRAWFORD:
 6 Q. No. 3 is a deposition notice for
 7 today's deposition. Do you recognize that?
 8 A. I do.
 9 Q. Have you looked at Exhibit A to
 10 that deposition notice or I should say Schedule
 11 A?
 12 A. Yes, I have.
 13 Q. Schedule A is a list of documents
 14 and tangible items that you were requested to
 15 bring with you to your deposition today; is that
 16 true?
 17 A. Do you know -- can you take a look
 18 at this, 'cause I don't think -- it's missing
 19 some pages. I don't think it actually says
 20 Schedule A anywhere.
 21 MR. ROSENBLATT: The version I have
 22 cuts off at page 7.
 23 THE WITNESS: Oh, is it on the back
 24 pages maybe.
 25 MR. ROSENBLATT: I think you maybe

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1 tried to print double-sided but it --
 2 Q. That one's double-sided.
 3 A. Okay. What was the question again?
 4 Q. Did you have an opportunity to
 5 review Schedule A?
 6 A. I have, yes.
 7 Q. And have you brought documents and
 8 tangible items with you today that are responsive
 9 to Schedule A?
 10 MR. ROSENBLATT: And I'll just note
 11 for the record that I think we filed objections
 12 but if we haven't, they will be filed, but you
 13 can answer.
 14 A. Right. So that was one of the
 15 reasons we met earlier, is that Attorney
 16 Rosenblatt brought things that I had provided to
 17 him, and so we went over those, which are sitting
 18 in front of me.
 19 Q. Okay.
 20 A. It's all yours (indicating).
 21 Q. There's a large number of, in my
 22 opinion, a large number of -- several folders
 23 containing documents sitting in front of me here
 24 at this conference table.
 25 Can you make an effort to summarize

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1 what's contained here?
 2 A. Sure. So first are my billing
 3 records for work done in these cases.
 4 Q. Okay. I'm going to mark that as
 5 Exhibit No. 4. Bear with me just a second.
 6 A. Yeah.
 7 Q. Actually, it appears to be two
 8 different documents; is that right?
 9 A. Correct.
 10 Q. Okay. I will mark the first one as
 11 Exhibit No. 4 and the second as Exhibit No. 5.
 12 (Whereupon, Deposition Exhibit 4,
 13 Invoice #2,
 14 was marked for identification.)
 15 (Whereupon, Deposition Exhibit 5,
 16 Invoice #1,
 17 was marked for identification.)
 18 BY MR. CRAWFORD:
 19 Q. And, again, for purposes of the
 20 record, Exhibits 4 and 5 are documents that
 21 relate to the work you've done on these files or
 22 on this case and the amount charged, correct?
 23 A. Correct.
 24 Q. While we have them out in front of
 25 us, there appears to be one invoice, specifically

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1 Invoice No. 1. It's dated June 12th, 2016.
 2 That's Exhibit No. 5; is that right?
 3 A. Yes.
 4 Q. And that invoice is for a total of
 5 \$63,200.
 6 A. Correct.
 7 Q. Then there's a second invoice
 8 that's marked as Exhibit No. 4, and that invoice
 9 is dated --
 10 A. Somehow that did not get translated
 11 properly.
 12 Q. So the invoice marked as
 13 Exhibit No. 4 doesn't have a date. However, it
 14 does have a --
 15 A. It was sometime after this date
 16 (indicating).
 17 Q. The invoice marked as Exhibit No. 4
 18 doesn't have a date at the top, but you believe
 19 that that invoice was generated at sometime after
 20 June 11th, 2016?
 21 A. Probably after June 12th.
 22 Q. Okay. And the amount for that
 23 invoice is \$21,200?
 24 A. Correct.
 25 Q. So to date, you've billed

<p style="text-align: right;">Page 26</p> <p>1 approximately \$84,400 for your services as an 2 expert witness in this case?</p> <p>3 A. Correct.</p> <p>4 Q. Does that include your time as a 5 general causation expert only or is that also 6 charges for the work you've done as a 7 case-specific expert?</p> <p>8 A. Both.</p> <p>9 Q. Okay, let's turn to the next 10 document or set of documents that you brought in 11 response to Schedule A to your deposition notice.</p> <p>12 A. Well, there are a number of folders 13 where there are PowerPoint presentations that 14 have been printed out, and the first set is 15 labeled TVT-O. The second set is labeled TVT-S. 16 The third group is referred to as additional 17 slides. The next are presentations labeled TVT 18 Exact. The next are presentations labeled TVT. 19 The next are presentations, yup, labeled 20 Prosima™. And the next are a group of 21 presentations labeled Ethicon.</p> <p>22 MR. ROSENBLATT: Jeff, I'll just 23 represent there are two copies of each 24 presentation or there should be two copies of 25 each presentation in there.</p>	<p style="text-align: right;">Page 28</p> <p>1 Exhibit No. 6 documents and things that you've 2 reviewed just prior to coming to your deposition 3 in preparation for this deposition?</p> <p>4 A. I honestly just scanned through 5 those to make sure those were the ones that I had 6 sent. But have I read all the slides, absolutely 7 not.</p> <p>8 Q. Of all the documents, the things 9 that you've reviewed in conjunction with being an 10 expert on transvaginal mesh, is there any 11 particular reason you chose these documents 12 marked as Exhibit No. 6 to refresh yourself on 13 and look at just prior to your deposition?</p> <p>14 A. They were not to refresh my memory. 15 They were just in response to Schedule A I guess 16 it is. Yeah, Schedule A. Any presentations that 17 had to do with the topics that we're discussing.</p> <p>18 Q. Returning to -- our attention to 19 Schedule A of your deposition notice, did you 20 bring with you a current copy of your curriculum 21 vitae?</p> <p>22 MR. ROSENBLATT: And I'll just 23 represent I think the current version was 24 attached as an exhibit to his general deposition. 25 Q. Is that true, Doctor?</p>
<p style="text-align: right;">Page 27</p> <p>1 THE WITNESS: My phone is on 2 vibrate, but I may be getting a text just 'cause 3 one of my partners has a patient who has a 4 significant problem, and I may get a text about 5 it, and I'll try not to let this interfere with 6 the deposition, but I just want to let you know 7 I'm not being rude if I check a text.</p> <p>8 Q. Of course. I completely 9 understand.</p> <p>10 I ran into one I got confused on. 11 Let's go off the record?</p> <p>12 (Discussion off the record.) 13 (Whereupon, Deposition Exhibit 6, 14 Presentations, was marked 15 for identification.)</p> <p>16 BY MR. CRAWFORD: 17 Q. Doctor, we've finagled with some 18 exhibits and documents. I'm holding in my hand 19 Exhibit No. 6 to your deposition, correct?</p> <p>20 A. Okay.</p> <p>21 Q. What is this?</p> <p>22 A. These are presentations that I've 23 given in the past that are related to the topics 24 that we're discussing.</p> <p>25 Q. And are the documents contained in</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Yes, it is.</p> <p>2 Q. No. 2 of Schedule A requires you or 3 requests you to bring with you any and all 4 documents in your possession including but not 5 limited to correspondence, notes, videos, CVs, 6 DVDs, flash or USB drives, photographs, databases 7 or materials in other form provided to you or 8 created by you which you relate to your opinions, 9 expected testimony or development of your 10 opinions in this litigation.</p> <p>11 Have you brought those with you 12 today?</p> <p>13 A. Anything that I thought was 14 relevant that I brought that I knew was 15 accessible.</p> <p>16 Q. Is that contained in Exhibit No. 6 17 or are there other documents that are responsive 18 to that particular request that aren't contained 19 in Exhibit No. 6?</p> <p>20 MR. ROSENBLATT: And, Jeff, I will 21 just again note for the record we have filed 22 objections to the notice and Schedule A.</p> <p>23 MR. CRAWFORD: I understand.</p> <p>24 A. Anything I thought that was 25 relevant that I could get my hands on are there.</p>

<p style="text-align: right;">Page 30</p> <p>1 You know, what comes to mind, for 2 instance, is there may be like marketing DVDs 3 that I received 15 years ago that I have no idea 4 where they exist. So I made the best effort I 5 could to bring what, you know, was asked of me. 6 Q. Very good. Referring to No. 5, 7 have you reviewed any deposition testimony in 8 preparation for this deposition today? 9 A. I've seen some depositions from 10 other experts that I have scanned through that 11 I've tried to read, and I briefly looked through 12 a deposition that I did for a Bard litigation 13 which was I think about two years ago. 14 Q. How long ago did you review the 15 deposition testimony of other experts? 16 A. It's varied over a number of weeks. 17 Well, I did look at one within the last two or 18 three days as well. 19 Q. Which one was that? 20 A. There was one -- I'm going to say 21 his name wrong. Sepulveda. 22 Q. Okay. 23 A. And Tomezsko. And there may have 24 been one other. Toglia. 25 Q. Are those the only deposition</p>	<p style="text-align: right;">Page 32</p> <p>1 were sent to me about those specific cases. 2 Q. Do you know off the top of your 3 head whether you've seen a photograph of Toni 4 Hernandez? 5 A. I would be happy to look at 6 anything and tell you if I have seen it. I just 7 don't remember off the top of my head. 8 Q. As you sit here right now, you 9 don't recall ever seeing a photograph of Toni 10 Hernandez? 11 A. I may have, but I don't want to 12 state that I did or didn't. I just don't 13 remember. But I'd be happy to look at a 14 photograph and -- if you showed me a photograph, 15 I would definitely be able to tell if I saw it 16 before. 17 Q. The invoices marked as Exhibits No. 18 4 and No. 5 to your deposition, do those include 19 any time sheets, invoices, time records or 20 billing records that record or document the work 21 you've performed in this case? 22 A. I'm not sure I -- 23 MR. ROSENBLATT: Object to form. 24 A. Yeah. I'm not sure I understand. 25 Sorry. I'm not sure I understand the question.</p>
<p style="text-align: right;">Page 31</p> <p>1 transcripts you can think of right now? 2 A. Off the top of my head, yes. 3 Q. Schedule A requests you to bring 4 with you those deposition transcripts. Did you 5 do that? 6 MR. ROSENBLATT: I'm just going to 7 object, Jeff. No, he didn't bring them with him. 8 Q. Did you review any pleadings in 9 connection with preparing for this deposition? 10 A. I guess I'm not familiar with that 11 term exactly. I've heard the term, but I don't 12 know if I've seen pleadings. 13 Q. Have you seen anything that you 14 think looks like it has been filed with the 15 court? 16 A. Not that I recall. 17 Q. You haven't brought any pleadings 18 with you today, have you? 19 A. I guess not. 20 Q. If you don't know what they are, 21 you haven't brought them then. 22 Do you have any photographs of any 23 of the case-specific plaintiffs that you're 24 involved in? 25 A. I don't recall if any photographs</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Do you have any other time sheets 2 or any other documents that reflect the specific 3 work you've done on this case, other than the 4 invoices that are marked as Exhibits No. 4 and 5 No. 5? 6 A. No. Everything I've done, that's 7 how I record it, and then I generate an invoice 8 based on that. 9 Q. Are there other documents other 10 than 4 and 5 that contain information that was 11 used to generate Exhibits No. 4 and 5? 12 A. No. 13 Q. Do you prepare these invoices 14 yourself? 15 A. I do. 16 Q. Using what software? 17 A. Word. I don't mean that like when 18 my son says word. I mean "Word." 19 Q. I noticed you didn't flash any gang 20 signs when you said that, so. 21 A. I felt funny when I said that. 22 Microsoft Word. 23 Q. There we go. The point is you 24 don't generate time sheets and then hand them to 25 someone who then uses that information to compile</p>

<p style="text-align: right;">Page 34</p> <p>1 or generate these invoices?</p> <p>2 A. No.</p> <p>3 Q. Something tells me you didn't bring</p> <p>4 with you copies of your Schedule C and Form 1099</p> <p>5 of your tax records for the preceding five years.</p> <p>6 MR. ROSENBLATT: You don't need to</p> <p>7 answer that. No, we're not producing that.</p> <p>8 Q. No. 14 requests that you produce</p> <p>9 all documents related to your involvement with</p> <p>10 Ethicon's professional education, including, but</p> <p>11 not limited to any and all PowerPoints, course</p> <p>12 materials, outlines, videos or presentations,</p> <p>13 live surgical presentations, marketing</p> <p>14 evaluations created by or provided to you related</p> <p>15 to any pelvic mesh product sold by Ethicon.</p> <p>16 Do you have any materials or items</p> <p>17 that fit that description other than what you</p> <p>18 have already produced and has been marked as</p> <p>19 Exhibit No. 6 to your deposition?</p> <p>20 A. The only thing I could think of</p> <p>21 besides what's already been produced is I did --</p> <p>22 I did personally create a video that was used by</p> <p>23 Ethicon for tensioning slings, and we can make</p> <p>24 that available. It's a short video on how to</p> <p>25 tension a sling.</p>	<p style="text-align: right;">Page 36</p> <p>1 bring with you any and all documents relating to</p> <p>2 any presentations, PowerPoints or lectures</p> <p>3 regarding any female pelvic mesh product used for</p> <p>4 treatment of stress urinary incontinence or</p> <p>5 pelvic organ prolapse.</p> <p>6 Have you brought those with you?</p> <p>7 MR. ROSENBLATT: And I'll just note</p> <p>8 our objection to being overbroad and vague.</p> <p>9 A. Well, I was going to ask you, are</p> <p>10 you talking about Ethicon products there?</p> <p>11 Q. The request specifically says any</p> <p>12 female pelvic mesh product used for treatment of</p> <p>13 stress urinary incontinence or pelvic organ</p> <p>14 prolapse.</p> <p>15 A. So I know that there are other</p> <p>16 presentations. I did not bring them. And with</p> <p>17 permission from counsel, I would be perfectly</p> <p>18 willing to provide those to you.</p> <p>19 Q. As you sit here today, what</p> <p>20 presentations are you aware of that you're in</p> <p>21 possession of that weren't brought with you</p> <p>22 today?</p> <p>23 A. Well, what comes to mind is that I</p> <p>24 in the last several years have been doing some</p> <p>25 teaching for Boston Scientific as well as some,</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. When was that video created?</p> <p>2 A. Oh, it's got to be ten years ago.</p> <p>3 Q. Where is it right now?</p> <p>4 A. It's -- where's the video?</p> <p>5 Q. Yes, sir.</p> <p>6 A. I mean, they made it into DVDs, and</p> <p>7 I most likely have a copy of the video on my</p> <p>8 computer.</p> <p>9 Q. Yes, sir, I would appreciate it if</p> <p>10 you'd produce that.</p> <p>11 Are we in agreement on that?</p> <p>12 MR. ROSENBLATT: If he's able to</p> <p>13 find it and send it to me, I'll pass it along to</p> <p>14 you.</p> <p>15 Q. Is there any particular reason you</p> <p>16 didn't bring that with you today?</p> <p>17 A. No. I'm happy to provide it,</p> <p>18 though.</p> <p>19 Q. Do there exist any transcripts or</p> <p>20 statements between you and any governmental</p> <p>21 agency regarding any pelvic mesh product used for</p> <p>22 treatment of stress urinary incontinence or</p> <p>23 pelvic organ prolapse?</p> <p>24 A. I don't believe so.</p> <p>25 Q. No. 18 requests that you produce or</p>	<p style="text-align: right;">Page 37</p> <p>1 you know, presentations that I've done on my own</p> <p>2 not in connection with Boston Scientific that</p> <p>3 have included the Uphold mesh device and before</p> <p>4 that Pinnacle.</p> <p>5 I think when I read this -- I'm</p> <p>6 only now seeing that it was just any treatment,</p> <p>7 and I was thinking about Ethicon and that's why I</p> <p>8 produced those.</p> <p>9 Q. If it had said Ethicon</p> <p>10 specifically, have you satisfied that requirement</p> <p>11 as set forth in No. 18?</p> <p>12 A. Yes.</p> <p>13 Q. We're through with the notice. Do</p> <p>14 you want to take a break?</p> <p>15 (A break was taken.)</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. Doctor, is it fair to say that the</p> <p>18 risks of you using mesh in pelvic reconstructive</p> <p>19 surgery are well-known?</p> <p>20 A. Yes.</p> <p>21 Q. And they've been well-known for a</p> <p>22 long time?</p> <p>23 A. Right, decades.</p> <p>24 Q. Some risks are common with pelvic</p> <p>25 reconstructive surgery regardless of whether mesh</p>

<p style="text-align: right;">Page 38</p> <p>1 is used?</p> <p>2 A. Correct.</p> <p>3 Q. Such as bleeding, infection, injury</p> <p>4 to adjacent organs, scarring and dyspareunia?</p> <p>5 A. Correct.</p> <p>6 Q. Then there's some risks that are</p> <p>7 unique to surgeries that involve the use of mesh,</p> <p>8 including mesh erosion into the surrounding</p> <p>9 organs?</p> <p>10 A. So when you put it that way, you</p> <p>11 know, erosion into surrounding organs can happen</p> <p>12 with any permanent material like suture. But</p> <p>13 when you say, quote/unquote, mesh erosion, you</p> <p>14 can't get -- you can't get erosion of mesh unless</p> <p>15 you use mesh. But we certainly see erosions of</p> <p>16 permanent sutures, for instance, into surrounding</p> <p>17 organs or into the vagina.</p> <p>18 Q. I understand that. I appreciate</p> <p>19 that clarification.</p> <p>20 But mesh erosion is unique to</p> <p>21 surgeries that involve the use of synthetic mesh?</p> <p>22 A. Correct.</p> <p>23 Q. Mesh erosion into surrounding</p> <p>24 organs such as the bladder and the urethra and</p> <p>25 the rectum are a known risk associated with</p>	<p style="text-align: right;">Page 40</p> <p>1 mesh placed through the vagina, including mesh</p> <p>2 erosion and exposure?</p> <p>3 MR. ROSENBLATT: And, Jeff, do you</p> <p>4 have a copy to show him or do you plan on marking</p> <p>5 that as an exhibit?</p> <p>6 MR. CRAWFORD: I don't. I'm making</p> <p>7 reference to it as it was described in his</p> <p>8 report.</p> <p>9 A. Just one second.</p> <p>10 (Discussion off the record.)</p> <p>11 A. I'm sorry, did you say that we did</p> <p>12 have a copy of the 2008 FDA Public Health</p> <p>13 Notification?</p> <p>14 MR. ROSENBLATT: I think he said he</p> <p>15 was just referring to your report.</p> <p>16 A. Okay, got it.</p> <p>17 Q. You're pretty familiar with that --</p> <p>18 A. Yes, I am.</p> <p>19 Q. -- aren't you?</p> <p>20 A. Yeah, I just wanted to know if Paul</p> <p>21 wanted to have it in front of me, but yes, I am.</p> <p>22 Q. I'll re-ask the question.</p> <p>23 A. Thank you.</p> <p>24 Q. The FDA stated that surgeons and</p> <p>25 patients should be aware of what it termed</p>
<p style="text-align: right;">Page 39</p> <p>1 Prolene® mesh, fair?</p> <p>2 A. Well, no. When you say Prolene®</p> <p>3 mesh -- Prolene® mesh is a trade name, right --</p> <p>4 Q. Sure.</p> <p>5 A. -- so it can happen with any</p> <p>6 polypropylene mesh. Fortunately mesh erosion</p> <p>7 into a surrounding organ is exceedingly rare as</p> <p>8 opposed to mesh exposures.</p> <p>9 Q. But it is a known risk. Whether</p> <p>10 it's rare or not it's a known risk?</p> <p>11 A. It is a known risk.</p> <p>12 Q. And for clarification, Prolene®</p> <p>13 mesh is a synthetic polypropylene mesh?</p> <p>14 A. It's one of the -- it's one type of</p> <p>15 polypropylene mesh.</p> <p>16 Q. And in October of 2008, the FDA</p> <p>17 issued a pelvic health notification regarding</p> <p>18 transvaginal mesh.</p> <p>19 A. Correct.</p> <p>20 Q. That would include Ethicon's</p> <p>21 Prolene® mesh, right?</p> <p>22 A. Correct.</p> <p>23 Q. The FDA stated that surgeons and</p> <p>24 patients should be aware of what's termed</p> <p>25 "serious complications" associated with surgical</p>	<p style="text-align: right;">Page 41</p> <p>1 "serious complications" associated with surgical</p> <p>2 mesh placed through the vagina including mesh</p> <p>3 erosion and exposure; is that right?</p> <p>4 A. That's correct.</p> <p>5 Q. And that would include Ethicon's</p> <p>6 Prolene® mesh as indicated?</p> <p>7 A. Yes.</p> <p>8 Q. In 2008, did the FDA warn the</p> <p>9 public that over the previous three years it</p> <p>10 received over 1,000 reports of complications that</p> <p>11 were associated with surgical mesh devices used</p> <p>12 to repair pelvic organ prolapse and stress</p> <p>13 urinary incontinence?</p> <p>14 A. That is correct.</p> <p>15 Q. And those devices also included</p> <p>16 those made with Ethicon Prolene® mesh, true?</p> <p>17 A. That is correct.</p> <p>18 Q. Was it noted by the FDA that the</p> <p>19 most frequent complications include exposure of</p> <p>20 the mesh through the vagina -- through the</p> <p>21 vaginal epithelium, infection, pain, urinary</p> <p>22 problems and recurrence of either prolapse or</p> <p>23 incontinence?</p> <p>24 A. Well, if I remember correctly, the</p> <p>25 most common was the mesh exposure, but those</p>

<p style="text-align: right;">Page 42</p> <p>1 others that you mentioned are also potential 2 risks but not necessarily related specifically to 3 mesh, but with any -- you know, infection can 4 happen, scarring can happen with any pelvic 5 surgery. 6 Q. Did the FDA in 2008 stress the need 7 for adequate informed consent and specialized 8 training for specific mesh kits? 9 A. Yes, they did. 10 Q. And did the FDA also stress the 11 need to be vigilant for mesh complications 12 including erosion and infection as well as 13 complications associated with the tools used in 14 the placement of transvaginal mesh? 15 A. Yes, they did. 16 Q. In 2008 did the FDA also recommend 17 that surgeons inform their patients that the 18 implantation of surgical mesh is to be considered 19 permanent and that some complications associated 20 with the mesh may require additional surgery? 21 A. Yes, they did. 22 MR. ROSENBLATT: It's on page 13 23 and 14. 24 THE WITNESS: Thank you. 25 Q. Finally, did the FDA in 2008 also</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Presumably, yes. 2 Q. Do you think that it was wrong for 3 the FDA to have told the public that 4 complications associated with transvaginal mesh 5 are not rare? 6 A. I think it was wrong of the FDA. 7 Q. Why? 8 A. As stated in my report, there were, 9 you know, 1503 reports to the FDA about 10 complications associated with mesh, and in the -- 11 in I believe it's the white paper that was 12 associated with the safety update, they talk 13 about that there were approximately 75,000 14 transvaginal mesh cases done in the United States 15 per year. And if you do the math, over that 16 three-year period, that's over 200,000 cases, and 17 you've got 1503 reports. So if you do the math, 18 it comes down to .06 percent which in my mind -- 19 if a doctor was operating on me and said your 20 chance of a serious complication was about a half 21 a percent, I would consider that pretty rare, 22 personally. 23 Q. Do you criticize the FDA for 24 opening the door to plaintiffs attorneys who've 25 now filed tens of thousands of cases against</p>
<p style="text-align: right;">Page 43</p> <p>1 encourage surgeons to inform their patients about 2 potentially serious complications affecting their 3 quality of life including pain during intercourse 4 and vaginal scarring? 5 A. Yes, they did. 6 Q. In 2011, the FDA issued an update 7 of that 2008 notification based on a continuing 8 analysis of adverse events that had been reported 9 to the FDA between 2008 and 2011. 10 A. Correct. 11 Q. While basically reiterating the 12 information from the 2008 public health notice, 13 the FDA went further in 2011 stating that the 14 complications noted in the 2008 notice were not 15 rare? 16 A. That's what they reported, correct. 17 Q. In fact, from January 1st, 2008, 18 through December 31st, 2010, the FDA had received 19 2,874 additional reports of complications 20 associated with surgical mesh devices used to 21 treat pelvic organ prolapse and stress urinary 22 incontinence? 23 A. Correct. 24 Q. Those devices would include the 25 devices made with Ethicon Prolene® mesh?</p>	<p style="text-align: right;">Page 45</p> <p>1 medical device manufacturers for transvaginal 2 mesh? 3 A. I think that's part of the 4 situation. I don't think it rests solely with 5 the FDA, but I think that contributed to it. 6 Q. What else do you believe 7 contributes to it? 8 MR. ROSENBLATT: Object to form. 9 A. I believe the fear mongering with 10 all the plaintiff ads on TV have done a real 11 disservice to women throughout this country. 12 Q. Anything else? 13 A. The only thing that comes to mind 14 are, you know, I recall seeing an article in 15 Reuters about medical lenders who are also taking 16 advantage of, I believe, the situation and taking 17 advantage of women who may have problems with 18 mesh. 19 Q. In what ways are they taking 20 advantage? 21 A. By lending patients money and 22 jacking up the bills artificially so that when 23 women get their settlements most of the 24 settlement money goes to the entrepreneurs and 25 not to the patients who have been hurt by these,</p>

<p style="text-align: right;">Page 46</p> <p>1 potentially hurt by these procedures. 2 Q. What evidence do you have that 3 that's going on? 4 A. Just an article that I read in 5 Reuters about this. 6 Q. Do you have any personal knowledge 7 regarding that going on? 8 A. Yes, my personal knowledge is my 9 discussions with a urogynecologist colleague of 10 mine named Dr. Cassidenti in the Los Angeles area 11 who was contacted by one of these medical lenders 12 and was asked to remove mesh in women and would 13 be paid cash to do this. 14 Q. Any other evidence? 15 A. Not that I can think of. 16 Q. Have you yourself been approached 17 by any such lenders? 18 A. I have not. 19 Q. You perform around 300 surgeries 20 for prolapse and incontinence every year? 21 A. Roughly. 22 Q. Approximately how many of those 300 23 surgeries that you perform each year involve the 24 use of Ethicon Prolene® mesh? 25 MR. ROSENBLATT: Object to form.</p>	<p style="text-align: right;">Page 48</p> <p>1 What percentage of your surgeries 2 last year involved Ethicon mesh, those two 3 products that you just referred to? 4 A. I would say of the -- I probably do 5 roughly 100 sling operations a year, maybe 100 to 6 125, and percentage-wise, probably 40 percent of 7 them are TVT-O, but that's been decreasing over 8 the last couple years. So maybe this year it's 9 probably more like 30 percent or 25 percent. 10 Q. So last year approximately 40 11 percent of your 100 sling operations involved the 12 use of Ethicon products? 13 A. I believe that's correct. 14 Q. And that number has decreased this 15 year? 16 A. Correct. 17 Q. Why? 18 A. Only because I'm using more of a 19 different transobturator sling. I still do a lot 20 of transobturator slings, but I'm using more of 21 the Boston Scientific slings at this point. 22 Q. Why did you switch? 23 A. Well, I haven't switched, but my 24 fear is that over the past -- 25 Q. And I'm sorry to cut you off. Let</p>
<p style="text-align: right;">Page 47</p> <p>1 Jeff, are you referring specifically to Prolene® 2 or are you using Prolene® more broadly? Just -- 3 MR. CRAWFORD: I want to know 4 Prolene®, how often does he use Ethicon's 5 Prolene® mesh. And my next question will be in 6 how many of those procedures do you use synthetic 7 mesh that's not Ethicon Prolene® mesh? 8 MR. ROSENBLATT: Jeff, I'm not 9 trying to be difficult but Gynemesh® PS is also 10 made from Prolene. So I'm just wondering are you 11 asking about Prolene® or Prolene in general. 12 Q. Prolene in general. 13 A. So it varies per year, but if you 14 want to know currently -- 15 Q. Yes, sir. 16 A. So I'm still using TVT-O, and 17 occasionally Gynemesh®. I think those are the 18 only two products that I'm currently using. 19 Q. Were you using those last year? 20 A. Yes. 21 Q. And last year you performed 22 approximately 300 surgeries? 23 A. Correct, but that wasn't the -- 24 that wasn't the only sling type that I was using. 25 Q. And that's what I'm getting at.</p>	<p style="text-align: right;">Page 49</p> <p>1 me rephrase the question so you don't have to 2 answer twice. 3 A. Sure. 4 Q. Why have you -- I don't mean to be 5 rude. I'm just trying to save you the time. 6 A. Are you talking to me? 7 Q. Yeah. 8 A. Okay. 9 Q. What is the reason that you've 10 decreased your use of Ethicon products and 11 increased your use of Boston Scientific products? 12 A. Right. So if I thought that I 13 could use the Ethicon products from now until the 14 day I retire, I would, but over the last couple 15 years, Ethicon has dropped their sales force, and 16 there are rumors that they may stop manufacturing 17 altogether. So I wanted to get prepared for that 18 day, and so I started looking at other sling 19 products from companies that I believe will 20 continue to be around for the long term, and 21 that's why I have transitioned myself slowly to 22 Boston Scientific. 23 Q. When did you begin that transition? 24 A. I would say not long after they 25 dropped their sales force.</p>

<p style="text-align: right;">Page 50</p> <p>1 Q. When was that?</p> <p>2 A. I don't remember precisely, but I'm</p> <p>3 going to say about three years ago.</p> <p>4 Q. Approximately 2013?</p> <p>5 A. I believe so.</p> <p>6 Q. In 2013, were you still performing</p> <p>7 approximately 100 sling procedures?</p> <p>8 A. 100 to 125, yeah.</p> <p>9 Q. Back then what percentage of your</p> <p>10 sling procedures involved the use of Ethicon</p> <p>11 mesh?</p> <p>12 A. I believe it was 100 percent.</p> <p>13 Q. And today, three years later,</p> <p>14 that's down to approximately 30 percent?</p> <p>15 A. Correct.</p> <p>16 Q. What's the BSC product that's</p> <p>17 comparable to the Ethicon product you're</p> <p>18 replacing it with?</p> <p>19 A. Yeah, it's not really comparable,</p> <p>20 but it's an outside-in as opposed to the</p> <p>21 inside-out transobturator sling, and it's called</p> <p>22 the Obtryx II. Roman numeral II, O-B-T-R-Y-X.</p> <p>23 Q. Back to the FDA. In conjunction</p> <p>24 with its 2011 update, did the FDA conduct a</p> <p>25 systematic review of the published scientific</p>	<p style="text-align: right;">Page 52</p> <p>1 Q. Is it fair to say that you</p> <p>2 recommend for the use of transvaginal mesh --</p> <p>3 strike that.</p> <p>4 Is it fair to say you recommend the</p> <p>5 use of transvaginal mesh in pelvic reconstructive</p> <p>6 surgery?</p> <p>7 A. Not as a general statement, but in</p> <p>8 select cases, I do.</p> <p>9 Q. You're not suggesting that mesh is</p> <p>10 recommended for all patients who are in need of</p> <p>11 surgical repair?</p> <p>12 A. Absolutely not.</p> <p>13 Q. There are alternatives to using</p> <p>14 synthetic mesh in pelvic reconstructive</p> <p>15 surgeries?</p> <p>16 A. There are.</p> <p>17 Q. Sometimes transvaginal mesh is the</p> <p>18 best option but sometimes an alternative may be</p> <p>19 the best option?</p> <p>20 A. That is correct.</p> <p>21 Q. Do you believe the FDA in its</p> <p>22 public health notices of 2008 and 2011 presented</p> <p>23 a biased view of transvaginal mesh?</p> <p>24 A. Yes.</p> <p>25 Q. Why?</p>
<p style="text-align: right;">Page 51</p> <p>1 literature to evaluate the safety and efficacy of</p> <p>2 transvaginal mesh for pelvic organ prolapse?</p> <p>3 A. Yes.</p> <p>4 Q. Did that systematic review</p> <p>5 demonstrate that transvaginal mesh repairs do not</p> <p>6 improve symptomatic results or qualify -- strike</p> <p>7 it.</p> <p>8 Did that systematic review</p> <p>9 demonstrate that transvaginal mesh repairs do not</p> <p>10 improve symptomatic results or quality of life</p> <p>11 over traditional non-mesh repair?</p> <p>12 MR. ROSENBLATT: Object to form.</p> <p>13 A. That's what they stated.</p> <p>14 Q. Did the literature review conducted</p> <p>15 by the FDA reveal that mesh used in transvaginal</p> <p>16 repairs introduces risks not present in non-mesh</p> <p>17 surgery for pelvic organ prolapse?</p> <p>18 A. That is what the FDA said.</p> <p>19 Q. Did the FDA discover in 2011 that</p> <p>20 there was no evidence that transvaginal repair to</p> <p>21 support the top of the vagina or the back wall of</p> <p>22 the vagina with mesh provided any added benefits</p> <p>23 compared with traditional surgery that did not</p> <p>24 use mesh?</p> <p>25 A. That is what the FDA stated.</p>	<p style="text-align: right;">Page 53</p> <p>1 A. For the reasons I already stated,</p> <p>2 that their interpretation of the -- whether or</p> <p>3 not serious complications were rare is based on</p> <p>4 their interpretation of the data. And, also, I</p> <p>5 think the bias is that any return trip to the</p> <p>6 operating room is considered a serious</p> <p>7 complication by the FDA but that return to the</p> <p>8 operating room may be a minor procedure such as</p> <p>9 excision of a few fibers of mesh that have been</p> <p>10 exposed in the vagina, and coupled along with</p> <p>11 that is that if a patient fails a prolapse repair</p> <p>12 with native tissue and has to go back to the</p> <p>13 operating room to have a whole another procedure</p> <p>14 done for her prolapse, that is not considered a</p> <p>15 serious AE, or adverse event, by the FDA, but</p> <p>16 it's a much bigger operation. So that, to me,</p> <p>17 demonstrates an inherent bias in their</p> <p>18 notifications.</p> <p>19 Q. Generally speaking, do you believe</p> <p>20 that a complication that requires a woman to go</p> <p>21 to the operating room for surgical repair of that</p> <p>22 complication is considered a serious</p> <p>23 complication?</p> <p>24 MR. ROSENBLATT: Object to form.</p> <p>25 A. So that is how the FDA sets up what</p>

<p style="text-align: right;">Page 54</p> <p>1 they consider a serious adverse event, is a 2 return trip to the operating room, and I'm not 3 taking that lightly at all. But from a clinical 4 standpoint, I would much rather -- if I had to 5 choose between taking someone back for a small 6 mesh exposure incision under local anesthesia 7 versus an entirely new operation to repair 8 recurrent prolapse with the inherent scarring 9 and... I would much rather, if I had to choose, 10 take the former rather than the latter. 11 Q. If I were to tell someone the 12 complication Woman A had is a serious 13 complication, and I know it was a serious 14 complication because it required her to go to the 15 emergency room to repair it, do you agree with 16 that statement? 17 MR. ROSENBLATT: Object to form. 18 A. I guess I'm not sure what you're 19 talking about in terms of going to the emergency 20 room. 21 Q. I meant operating room. I'm sorry. 22 I got to re-ask it. 23 A. Please. 24 Q. If I were to tell someone Ms. Smith 25 has a serious complication with her transvaginal</p>	<p style="text-align: right;">Page 56</p> <p>1 don't disagree with that. I'm talking about the 2 hypocrisy about not considering a return trip to 3 the operating room for recurrent prolapse not a 4 serious adverse event, that's all. 5 Q. Do you have any reason to believe 6 that what you consider to be a misrepresentation 7 of the data by the FDA was intentional on the 8 FDA's part? 9 MR. ROSENBLATT: Object to form. 10 A. I have no reason to believe that. 11 Q. For example, do you believe that 12 the FDA has some kind of a vendetta against 13 synthetic mesh manufacturers? 14 A. No, I don't believe that is true at 15 all. 16 Q. Can you imagine any reason why 17 anyone at the FDA would want to mislead the 18 public with a biased view of risks associated 19 with the use of transvaginal mesh to treat 20 women's health issues? 21 A. I can't think of any reason why 22 they would want to do that. 23 Q. Two risks unique to transvaginal 24 mesh include mesh exposure through the vaginal 25 wall and also erosion, which is the migration of</p>
<p style="text-align: right;">Page 55</p> <p>1 mesh, and the reason I know it's a serious 2 complication is because she had to go to the 3 operating room to have it repaired, do you think 4 I'm making a fair statement? 5 A. I guess what I'm saying is I don't 6 think that's unreasonable. What I'm saying is to 7 consider that a serious complication but not to 8 consider a recurrent prolapse requiring a whole 9 new operation for prolapse, not considering that 10 a serious complications is somewhat hypocritical. 11 Q. I understand. And I don't mean to 12 belabor the point, but is it fair to say that by 13 it's very def- -- strike it. 14 Is it fair to say that a 15 complication that requires a woman to go to the 16 operating room for a surgical repair that by its 17 very nature should be considered a serious 18 complication? 19 MR. ROSENBLATT: Object to form. 20 Asked and answered. 21 A. I think that that is reasonable, 22 but there are different degrees of serious 23 adverse events. And if the FDA wishes to 24 categorize that as a serious adverse event 25 because it's a return to the operating room, I</p>	<p style="text-align: right;">Page 57</p> <p>1 the mesh, into other organs. Is that right? 2 A. Right. 3 Q. Do you hold the opinion that most 4 cases of mesh exposure are minor complications 5 and are even asymptomatic? 6 A. That's true much of the time, 7 correct. 8 Q. On what studies or peer-reviewed 9 medical literature is that opinion based? 10 A. It's actually based on many studies 11 throughout the literature that many of the mesh 12 exposures are asymptomatic and that many mesh 13 exposures require either just an in-office 14 procedure or just observation or treatment with 15 estrogen cream. And, in addition, that's been my 16 experience for the past, you know, 15 years or so 17 in my clinical practice, that most of the mesh 18 exposures are either asymptomatic or minimally 19 bothersome to a patient. 20 Q. And by most, you mean the majority? 21 A. The majority, correct. 22 Q. Can you identify off the top of 23 your head any particular peer-reviewed literature 24 that supports that opinion? 25 A. Yes. I'd have to look to</p>

<p style="text-align: right;">Page 58</p> <p>1 specifically mention names, but a number of the 2 RCTs on Prolift. I believe Hiltunen. I believe 3 Nieminen. I'm probably saying that wrong. Talk 4 about how often mesh exposures are asymptomatic. 5 Q. Any others off the top of your 6 head? 7 A. No, but I'd be happy to look at 8 any, and there are many. It's throughout the 9 literature. 10 MR. ROSENBLATT: Did you want him 11 to go through his expert report and pull out any 12 references for you? 13 MR. CRAWFORD: No, I don't need 14 that. I just wanted to know what he could think 15 of off the top of his head. Thank you, though. 16 Do you hold the opinion that 17 there's a significantly higher rate of recurrent 18 prolapse with native tissue repair as compared to 19 use of transvaginal mesh. 20 A. Yes. 21 Q. On what studies or peer-reviewed 22 medical literature is that opinion based? 23 A. On many. I mean, even the RCTs 24 such as Altman and several others that, you know, 25 I'm familiar with but just don't come to mind,</p>	<p style="text-align: right;">Page 60</p> <p>1 they don't talk about cancelling the native 2 tissue repairs because of over 15 percent 3 exposure rate. 4 Q. You say in your report that the 5 Gynemesh® PS mesh used in Prolift is not 6 defective just because a small percentage of 7 patients may experience exposures or other 8 well-known and acceptable complications. 9 A. Correct. 10 Q. In your opinion, what percentage of 11 Prolift patients would have to experience mesh 12 exposures for you to consider the Prolift device 13 defective? 14 MR. ROSENBLATT: Object to form. 15 A. So I don't think there's a specific 16 number, and different studies show different 17 exposure rates. So I think a lot of it has to do 18 with technique, surgeon technique, as well as, 19 you know, the factors associated with the 20 patient. You know, clinical factors, like age 21 and estrogenization and menopausal status, 22 obesity, comorbidities like diabetes. But, to 23 me, that does not, a specific percentage does not 24 denote a defect in the product itself. 25 Q. So there is no particular specific</p>
<p style="text-align: right;">Page 59</p> <p>1 but I've read many, many RCTs as well as -- well, 2 the RCTs, that the rate of recurrent prolapse is 3 much higher with native tissue repairs. 4 Q. For the benefit of a jury, what is 5 an RCT? 6 A. Oh, RCT. It's a randomized 7 controlled trial. 8 Q. Do you agree that there's no chance 9 of mesh erosion or exposure with a native tissue 10 repair? 11 MR. ROSENBLATT: Object to form. 12 A. That's true when you use the word 13 mesh, but it's certainly not true with native 14 tissue repairs that use permanent synthetic 15 materials where there's a risk of erosion. And, 16 you know, in fact, just that you mentioned it, 17 the one that leaps off my mind is the Iglesia RCT 18 comparing Prolift to native tissue repair that 19 was stopped during an interim analysis because 20 the mesh exposure rate was over 15 percent, which 21 was a predetermined percentage at which they 22 would stop the procedure, but in the same 23 article, they talk about the native tissue 24 repairs showing a GORE-TEX exposure rate of over 25 15 percent as well, but they don't -- you know,</p>	<p style="text-align: right;">Page 61</p> <p>1 percentage at which you would say this is a 2 defective product? 3 MR. ROSENBLATT: Object to form. 4 Asked and answered. 5 A. No, only in that different 6 studies -- you know, I've seen exposure rates as 7 high as 20 percent. I've seen exposure rates of 8 5 percent or 2 percent. So, you know, every 9 study is different, and you're going to have 10 different exposure rates. 11 Q. Your report says the medical 12 literature commonly reports that eight or nine 13 out of ten women who have Prolift report that the 14 Prolift surgery improved their quality of life, 15 correct? 16 A. Correct. 17 Q. What medical literature are you 18 referring to or relying upon to make that 19 statement? 20 A. Can I take a look at -- 21 MR. ROSENBLATT: I think you've got 22 it. 23 THE WITNESS: Oh, I do? 24 Q. Page 46. The very first sentence 25 on page 46.</p>

<p style="text-align: right;">Page 62</p> <p>1 A. Oh, thank you. You know, as an 2 example, the article I quote with Feiner from 3 2010 shows that despite some patients developing 4 de novo dyspareunia, the overwhelming majority, 5 in this case 94 percent of the women, say they 6 would have had the same surgery again, and over 7 90 percent would recommend it to a friend. 8 Q. Is there anything other than the 9 Feiner report in 2010 on which you base your 10 opinion that the medical literature commonly 11 reports that eight or nine out of ten women who 12 have Prolift report that the Prolift surgery 13 improved their quality of life? 14 A. I believe that there -- there is 15 other literature, and I'm trying to remember. I 16 believe possibly Lowman, L-O-W-M-A-N, discusses 17 that as well. That they specifically looked at 18 dyspareunia rates, but that most women were very 19 satisfied with the procedure, and that even the 20 dyspareunia was considered mild for most women. 21 Q. Are there any other studies? 22 A. There are -- 23 MR. ROSENBLATT: Object to form. 24 A. -- but nothing that comes to mind. 25 Q. What year was the Lowman study?</p>	<p style="text-align: right;">Page 64</p> <p>1 A. I believe he's a urogynecologist. 2 Q. Do you know Dr. Rosenzweig 3 personally? 4 A. I may have met him many, many years 5 ago. 6 Q. Do you have any specific 7 recollection of that? 8 A. Yeah, I remember he taught at a 9 course I attended in the late 1990s. I believe 10 it was actually in Frisco, Colorado. And then he 11 sort of disappeared off the grid for a number of 12 years before he resurfaced. 13 MR. CRAWFORD: I will respectfully 14 object to the non-responsive portions of that 15 answer. 16 MR. ROSENBLATT: I think he's 17 referring to his skiing videos. 18 BY MR. CRAWFORD: 19 Q. Was there anything -- I mean, no 20 offense, but the late 1990s has been a while. 21 Is there any particular reason you 22 recall meeting Dr. Rosenzweig at that conference? 23 A. No, just that I remember him 24 lecturing at a conference I attended out there. 25 Q. Do you recall what topic or subject</p>
<p style="text-align: right;">Page 63</p> <p>1 A. What year was the Lowman study? 2 Q. Yes. Do you recall? 3 A. I don't recall off the top of my 4 head. 5 Q. Okay. 6 A. 2008. 7 Q. Thank you. What's your 8 understanding of Bruce Rosenzweig's role in this 9 case? 10 MR. ROSENBLATT: Object to form. 11 A. I know that Dr. Rosenzweig has been 12 identified as an expert for the plaintiff. 13 Q. Do you know anything beyond just 14 the fact that he is an expert for the plaintiff? 15 Do you know what he is an expert in? 16 MR. ROSENBLATT: Object to form. 17 Assumes facts not in evidence. 18 Q. Let me rephrase. 19 Do you know what subjects Bruce 20 Rosenzweig is held out to be an expert by the 21 plaintiffs' lawyers in this case? 22 A. Not specifically, although I've 23 read his report and I believe he discusses the 24 specific qualities of mesh, mesh properties. 25 Q. And do you know his specialty?</p>	<p style="text-align: right;">Page 65</p> <p>1 he lectured on? 2 A. No. 3 Q. What do you know about 4 Dr. Rosenzweig's reputation in the medical 5 community? 6 A. Only that he is -- I've seen his 7 name in connection with a number of legal cases 8 as a plaintiff expert. Not just limited to 9 Ethicon but in a number of cases. 10 Q. Anything else? 11 A. No. 12 Q. Do you have any reason to believe 13 Dr. Rosenzweig is a biased witness in this case? 14 A. I have no knowledge about anything 15 like that. 16 Q. Dr. Rosenzweig has opined that 17 Ethicon's Prolene® mesh is not suitable as a 18 permanent implant for pelvic reconstructive 19 surgery because the pores are too small. Do you 20 agree with that? 21 A. No. 22 Q. Why not? 23 A. So the Prolene® mesh, you know, has 24 been used in literally, you know, millions of 25 sling cases with phenomenal results.</p>

<p style="text-align: right;">Page 66</p> <p>1 I mean, if anything, you know, the 2 TVT products have revolutionized the field of 3 urogynecology, and that's not just from my 4 personal experience, which it is, but it's also 5 from, you know, hundreds of peer-reviewed, if not 6 thousands of peer-reviewed, articles about the 7 success of the material. 8 Q. I understand that you're an 9 advocate of the mesh, the synthetic mesh and the 10 use of synthetic mesh in pelvic reconstructive 11 surgery, but my question is a little more narrow, 12 and that is do you agree with the opinion that 13 the pores are too small in the Ethicon Prolene® 14 mesh? 15 MR. ROSENBLATT: Object to form. 16 A. Right, I don't agree with that. 17 And the reason is that the Prolene® mesh is a 18 macroporous Type 1 monofilament material that 19 undergoes excellent integration into patients' 20 tissues, which I have seen on countless cases, 21 and I think it's completely appropriate and 22 probably the most appropriate in that it also has 23 great qualities in terms of being tension free 24 and not moving and incorporating well into 25 tissue.</p>	<p style="text-align: right;">Page 68</p> <p>1 from this one device, there's no comparison. 2 There's no other procedure that's been as 3 successful to help women with these problems. 4 Q. I'll respectfully object to the 5 non-responsive portions of the answer other than, 6 yes, there are exceptions. 7 MR. ROSENBLATT: Doctor, you can 8 answer however you see fit. 9 Q. And you know I mean no disrespect 10 by those objections. 11 A. I understand. I appreciate that. 12 Q. I have to respectfully move to 13 strike portions of your answers that I don't 14 believe are responsive to my questions. 15 You understand that, right? 16 A. I do understand that. 17 Q. You've been deposed before, haven't 18 you? 19 A. I have. 20 Q. That doesn't hurt your feelings, 21 does it? 22 A. No, not all. Thank you for saying 23 that. 24 Q. I'll represent to you that 25 Dr. Rosenzweig also holds the opinion that</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. You said that it has a history of 2 excellent integration into human tissue? 3 A. Correct. 4 Q. Does that happen 100 percent of the 5 time? 6 A. What I have seen in my own clinical 7 practice is that it does. I mean, can you get 8 exposures, yeah, that's possible. 9 Fortunately, you know, Prolene® 10 mesh which is used for slings such as TVT and 11 TVT-O has an extremely low exposure rate of about 12 1 percent, and so, you know, I guess those are 13 the exceptions when you don't get tissue 14 integration. But for the vast majority of cases, 15 there's excellent integration with the tissue. 16 Q. But there are cases where that 17 doesn't occur? 18 A. But that can also occur with 19 Prolene® suture, and there are, you know, mesh -- 20 you know, suture exposures in the vagina that 21 happen with suture, and the suture has been 22 around for over five decades. 23 So, yes, there are always going to 24 be exceptions, but when you think of the 99 25 percent of women whose lives have been improved</p>	<p style="text-align: right;">Page 69</p> <p>1 polypropylene mesh is not suitable as a permanent 2 implant due to its heavy weight. 3 Does the weight of polypropylene 4 mesh have a bearing on whether or not it's 5 suitable for use in pelvic reconstructive 6 surgery? 7 A. So I respectfully disagree with his 8 opinion that it's a heavy weight mesh. It is 9 considered a lightweight mesh by the -- you know, 10 by classifications in the urogynecologic 11 literature. 12 Q. Is there something known as old 13 mesh as opposed to new mesh? 14 MR. ROSENBLATT: Object to form. 15 A. I haven't heard that specifically, 16 those terms. 17 Q. You've never seen the internal 18 Ethicon documents where Ethicon representatives 19 refer to some types of Ethicon mesh as old mesh? 20 MR. ROSENBLATT: Object to form. 21 Mischaracterization of the documents. 22 A. I don't recall seeing that, but I'd 23 be happy to look at any documents you want me to 24 look at. 25 Q. The notion that there's a old mesh</p>

<p style="text-align: right;">Page 70</p> <p>1 and a new mesh, that's a foreign concept to you 2 as you sit here today? 3 A. Well, I can imagine what you're 4 referring to. 5 You know, for instance, I think 6 of -- you know, polypropylene mesh is like 7 Marlex® mesh, being a heavier mesh than the 8 current meshes, but I would consider Prolene® 9 mesh, which is the mesh used for TVT and TVT-O 10 and TVT Abbrevio, for instance, and TVT Secur as 11 being a newer lightweight Type 1 macroporous 12 monofilament mesh. 13 Q. Okay. That stated, do you believe 14 that the weight of a mesh, synthetic mesh, would 15 have a bearing upon whether or not it's suitable 16 for pelvic reconstructive surgery? 17 A. So taking with what I said that 18 these are considered lightweight meshes, I 19 suppose that you could have heavier meshes than 20 what we're talking about that may not be 21 appropriate, but I'd have to know exactly which 22 meshes you're referring to. 23 Q. Well, in what ways can you conceive 24 of that a heavier mesh would be inappropriate for 25 an implant?</p>	<p style="text-align: right;">Page 72</p> <p>1 MR. ROSENBLATT: Object to form. 2 A. No, I think what the literature 3 shows and mesh science shows is that if you have 4 microporous mesh it's possible that you may 5 not -- for instance, you may not get good tissue 6 integration throughout the mesh, but also, the 7 possibility that bacteria could get into the 8 interstices of the mesh and the body's ability to 9 fight those bacteria with macrophages might be 10 compromised, but I don't think that has anything 11 to do with the Prolene® mesh that we're talking 12 about. 13 Q. I'll represent to you that 14 Dr. Rosenzweig holds the opinion that 15 polypropylene is not suitable as a permanent 16 implant because it causes chronic foreign body 17 reactions. 18 Do you agree with that? 19 A. No. 20 Q. Why not? 21 A. There are many implants that are 22 used throughout surgical interventions, including 23 anything from artificial hips to pacemakers to 24 mesh, to hernia mesh, which incite a foreign body 25 reaction. That's a normal response of the body</p>
<p style="text-align: right;">Page 71</p> <p>1 MR. ROSENBLATT: Object to form. 2 A. Well, bearing in mind that we're 3 not talking about the meshes that I just 4 described, you know, if you had a mesh which had 5 extremely limited pore size, that might affect 6 the ability of the mesh to incorporate. And in 7 my mind, you know, I'm not thinking about 8 specifically Ethicon meshes, but I think of other 9 meshes that are, for instance, woven, like the 10 IVS mesh or the ObTape which are much less 11 porous, and so I guess I'm thinking about those 12 being heavier meshes which did have issues with 13 them. 14 Q. The heavier the mesh, the smaller 15 the pore size? 16 MR. ROSENBLATT: Object to form. 17 A. Not necessarily, right? You can 18 have a very wide open weave with, depending on 19 what the weave is, with a heavier mesh, with a 20 heavier diameter of the strands. So I don't 21 think there's a direct correlation between the 22 diameter of the strands and the pore size. 23 Q. Do you believe that the smaller the 24 pore size, the more problems it can create for 25 the woman?</p>	<p style="text-align: right;">Page 73</p> <p>1 to a foreign object. That doesn't translate -- 2 there's no correlation between that and the 3 development of problems such as, you know, pelvic 4 pain or dyspareunia. So it's sort of apples and 5 oranges. Just because you may get a foreign body 6 reaction does not mean that's an untoward effect 7 toward the implant. 8 Q. Is there a difference between a 9 transitory foreign body reaction and a chronic 10 foreign body reaction? 11 A. I believe it is possible to get a 12 transient versus a permanent, a foreign body 13 reaction, but that again doesn't translate into a 14 clinically significant problem. 15 Q. What is the difference between -- 16 I'm using the word transitory, and you said 17 transient. Am I calling it the wrong thing? 18 A. I believe that those are 19 synonymous. 20 Q. Okay. I'm just going to say 21 transitory because that's how I know it. 22 A. Okay. 23 Q. Is there a difference between a 24 transitory foreign body response and a chronic 25 foreign body response?</p>

<p style="text-align: right;">Page 74</p> <p>1 A. Well, I think the way you're using 2 it and the way I'm using it I believe that one 3 with time it tends to go away, and one would be 4 sort of a permanent reaction, but I'm not aware 5 of any literature that shows that that translates 6 into a clinical difference for the patient. 7 Q. When you're talking about foreign 8 bodies inserted into a woman's vagina, is the 9 difference between a transitory foreign body 10 response and a chronic foreign body response a 11 significant distinction to make? 12 A. From a clinical standpoint, I don't 13 believe that's true. 14 Q. Why not? 15 A. Because I don't know any literature 16 that has shown that to be the case. 17 Q. You don't know of any literature 18 that shows that synthetic transvaginal mesh 19 causes chronic foreign body reactions? 20 A. That's not what I said. What I'm 21 saying is that has not translated into a 22 clinically significant difference, whether it's 23 chronic or transitory. 24 MR. ROSENBLATT: Once you finish 25 this line of questioning, if we could take a</p>	<p style="text-align: right;">Page 76</p> <p>1 something that's been implanted into her vagina? 2 A. Right, so fortunately infection of 3 mesh that we use in the vagina for either slings 4 or prolapse is exceedingly rare, and I can think 5 of -- of the over 2,000 slings or mesh that I've 6 put into a woman, I can think of one case where 7 an infection required me to remove the mesh. 8 That's a very low percentage. 9 Q. You have had a patient who had a 10 chronic foreign body response to transvaginal 11 synthetic mesh that required you to go in and 12 remove the mesh because it caused recurrent 13 infections? 14 MR. ROSENBLATT: Object to form. 15 Misstates the testimony. 16 A. Yeah, that's not what I'm saying at 17 all. 18 Q. I'm trying. I'm trying. 19 A. Okay. It actually wasn't recurrent 20 infections. It was a patient who had a TVT-O 21 obturator sling who within the first week of 22 surgery developed a serious infection which 23 required me to remove the mesh probably within 24 four days of the insertion. 25 Q. What caused that infection?</p>
<p style="text-align: right;">Page 75</p> <p>1 break. 2 Q. Help us understand what you mean by 3 clinical difference. 4 A. In other words, what is the 5 difference for the patient, that's what I mean by 6 clinical difference. 7 In other words, if you take 8 biopsies and you show that there's a chronic 9 versus a transitory or transient foreign body 10 response, that doesn't translate or correlate 11 with a patient's symptoms, so it may be 12 inconsequential, even though on a pathological 13 report you may see a chronic foreign body 14 response versus one that's transitory. 15 Q. So you don't think it's a more 16 serious issue for a woman to be facing a chronic 17 foreign body response than it is to be facing a 18 transitory foreign body response? 19 A. I have not seen literature that 20 suggests that a chronic foreign body response 21 translates to a clinical difference for a 22 patient. 23 Q. Well, a chronic foreign body 24 response could be recurrent infections for a 25 woman who's having foreign body response to</p>	<p style="text-align: right;">Page 77</p> <p>1 A. The causative agent was I believe 2 Group A Strep which is a very serious infection. 3 Q. Do you have any idea how that mesh 4 got infected with the Strep? 5 A. No. 6 Q. Based upon a reasonable degree of 7 medical probability, did it occur as the mesh was 8 being inserted into her vagina? 9 A. I think that's a reasonable 10 assumption. 11 Q. In other words, did it pick up some 12 Strep on its way in? 13 A. I believe that's reasonable, but 14 that's exceedingly rare. 15 MR. CRAWFORD: You want to take a 16 break? 17 MR. ROSENBLATT: Yeah. 18 (A break was taken.) 19 BY MR. CRAWFORD: 20 Q. Doctor, we are back from a break. 21 At the risk of beating a dead horse, we have to 22 talk just a little bit longer about this 23 transitory versus chronic, okay? 24 A. Sure. 25 Q. To let you know where I'm coming</p>

<p style="text-align: right;">Page 78</p> <p>1 from, I'll represent to you the plaintiffs in 2 this case are going to criticize Ethicon for 3 warning physicians that their synthetic mesh 4 could cause a transitory foreign body response 5 but not going that extra step and advising it 6 could cause a chronic foreign body response. 7 Do you follow me so far? 8 A. Yes. 9 Q. I gather from your testimony that 10 you don't think that's a fair criticism. 11 A. I agree. 12 Q. Why? 13 A. From what I've already stated, 14 which is that that does not -- I've never seen 15 any literature or in my personal experience doing 16 this for, you know, 20 years that any kind of 17 response to a foreign material translates into a 18 clinically significant problem, and I'll give you 19 an example. We implant -- we implant pacemakers. 20 I'm not talking about cardiologists. I'm talking 21 about urogynecologists implant pacemakers for 22 overactive bladder, for fecal incontinence, for 23 urinary retention. That's a foreign body. The 24 body responds to that by walling off the device, 25 and I guarantee you a metal pacemaker is not</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. And what else? Strike that. 2 How does the body respond to a 3 foreign body? 4 A. In many different ways, but often 5 it's with fibrosis, but you know, you get 6 fibrosis just with any surgery in the body. You 7 know, think of a scar on your arm if you cut 8 yourself or a keloid, that's scar tissue. So 9 that's a normal response to healing. 10 Another normal response in this 11 case to a foreign body is to try to wall off the 12 foreign body or try to cause scarring or fibrosis 13 around the foreign body, and that is a foreign 14 body response. That doesn't mean it's a bad 15 response. That's a pathologic diagnosis. But we 16 know, and in this case, we have literally 17 millions of women who've had the surgery, and 18 it's done -- you know, and it's been so 19 beneficial for these women. So having a foreign 20 body does not mean that it's a bad response of 21 the body to a foreign material. 22 Q. Move to strike the non-responsive 23 portions of that answer. 24 A foreign body response is not 25 necessarily a bad thing, correct?</p>
<p style="text-align: right;">Page 79</p> <p>1 porous. So you get a walled off -- you know, 2 that's one response to a foreign body. You may 3 do pathologic studies, if you want, and show that 4 you may have a chronic foreign body response 5 'cause the body sees that has a foreign body. 6 Patients are asymptomatic. It's irrelevant what 7 the body is doing as long as the patient doesn't 8 have a bad reaction to it, clinically. 9 Q. And I think that's the point is -- 10 I think what we're doing is equating chronic 11 foreign body responses to chronic recurrent 12 infections in women. 13 A. When you say "we," who are you 14 talking about? 15 MR. ROSENBLATT: Object to form. 16 Q. Is it fair to equate chronic 17 foreign body responses to chronic recurrent 18 infections in these women? 19 A. No, it's not fair because a foreign 20 body response has nothing to do with infection. 21 That would be a chronic infection. That's not 22 the same thing as a chronic body reaction. 23 Q. The body's reaction to a foreign 24 body is inflammation, right? 25 A. Usually initially.</p>	<p style="text-align: right;">Page 81</p> <p>1 A. Right, and also, it doesn't equate 2 to infection. 3 Q. A foreign body response is not a 4 bad thing, correct? 5 A. Correct. 6 Q. Unless it creates symptoms for the 7 woman. 8 MR. ROSENBLATT: Object to form. 9 A. Well, I think there's -- I have to 10 disagree. 11 Q. Okay. 12 A. There's a foreign body response, 13 but then there are possibly effects that are 14 separate from that foreign body response such as 15 exposure. Exposure of mesh which can occur 16 doesn't mean that it happened because of a 17 foreign body response. Exposures can be caused 18 by other things like a hematoma or a suture line 19 that opened up. So I think what you're doing is 20 equating a foreign body response with chronic 21 infection, and that's just not -- that's just not 22 how it happens. 23 Q. What about -- what about equating a 24 chronic foreign body response to chronic symptoms 25 such as pain, dyspareunia, and -- go ahead.</p>

<p style="text-align: right;">Page 82</p> <p>1 MR. ROSENBLATT: Object to form. 2 A. So I'm glad you brought that up. 3 And there was -- there are studies that have 4 looked at this. I can't remember what the first 5 author's name is, but there was one study which 6 was a great idea. They removed pieces of mesh 7 from women who needed a revision of their slings, 8 which is not that unusual, right? 9 So someone who develops urinary 10 retention or overactive bladder or some other 11 type of voiding dysfunction occasionally -- you 12 know, I do these surgeries -- we have to bring 13 women back for revision of the mesh which is 14 usually just cutting the mesh. 15 What these researchers did was to 16 take out a portion of the mesh and look at it 17 under the microscope, send it to pathology. And 18 they actually found that the women who had their 19 mesh removed for voiding dysfunction had more 20 foreign body reaction than the women that had 21 pain. So there was no correlation between 22 foreign body reaction and pain. There was 23 actually more foreign body reaction with voiding 24 dysfunction. So you cannot equate pain with 25 foreign body reaction.</p>	<p style="text-align: right;">Page 84</p> <p>1 strong oxidizers such as peroxides which are 2 readily found in the vagina. 3 Is he wrong about that? 4 A. I don't agree with his statement at 5 all for several reasons. 6 One is that Prolene® mesh is simply 7 made up of polypropylene fibers which we've been 8 using for over 50 years. I've gone back in on a 9 personal, you know, anecdotal level, and I've 10 seen Prolene® sutures that have been placed a 11 decade before I've been there, and I've seen no 12 evidence of any degradation of the Prolene®. 13 I've removed Prolene® mesh before and have not 14 seen any degradation of the mesh. 15 And in addition, and I can't speak 16 for all polypropylene, but I know with Prolene® 17 that there are specifically antioxidants that are 18 proprietary that resist oxidation. 19 Q. So the basis for your opinion -- 20 strike that. 21 The basis for you disagreeing with 22 Dr. Rosenzweig's opinion is that you've seen 23 polypropylene sutures in women that have been 24 there for a long time and they hadn't oxidized or 25 degraded, therefore other synthetic meshes</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. You cannot equate pain with a 2 foreign body response to synthetic mesh? 3 A. Correct. 4 Q. What study were you just referring 5 to? 6 A. I don't remember the first author, 7 but I'm happy to -- 8 Q. Well, there's been several times 9 where I've said, nah, you don't have to look that 10 up, but that was a pretty significant answer, so 11 I'd like to know the name of that study. 12 A. Okay. 13 MR. ROSENBLATT: We can try to get 14 it during a break. 15 MR. CRAWFORD: Okay, that sounds 16 good. 17 A. I'll make a note. 18 Q. Dr. Rosenswine -- excuse me. 19 Dr. Rosenzweig -- 20 A. Is that a Freudian slip? 21 Q. Dr. Rosenzweig opines that 22 Ethicon's Prolene® mesh is not suitable for 23 permanent implant because the material safety 24 data sheet for polypropylene resin used to make 25 polypropylene states that it's incompatible with</p>	<p style="text-align: right;">Page 85</p> <p>1 shouldn't oxidize or degrade; is that right? 2 MR. ROSENBLATT: Objection to form. 3 A. No, that's one example, but also, 4 I'm familiar with the literature that has looked 5 at this. I'm familiar with the scanning electron 6 microscopy which in some people's eyes has looked 7 like it has shown evidence of cracking and 8 degradation, but I'm also familiar with other 9 studies that have shown that that's a biofilm, 10 that the cracking is not in the polypropylene 11 itself, and if you wash it away, you get pristine 12 polypropylene. So I am not aware of any 13 definitive literature in humans that has shown 14 that there's degradation from oxidation of 15 Prolene® mesh. 16 Q. I got to go back and clean that up 17 a bit. 18 Dr. Rosenzweig opines that 19 Ethicon's Prolene® mesh is not suitable for 20 permanent implant because the material safety 21 data sheet for polypropylene resin used to make 22 the mesh said it's incompatible with strong 23 oxidizers such as peroxides which are readily 24 found in the vagina. And you disagree with that 25 opinion, correct?</p>

<p style="text-align: right;">Page 86</p> <p>1 A. Correct.</p> <p>2 Q. And one of the reasons that you</p> <p>3 disagree with that opinion is because you're</p> <p>4 unaware of any medical literature that indicates</p> <p>5 degradation due to oxidation of polypropylene</p> <p>6 mesh?</p> <p>7 A. No, I said of Prolene® mesh.</p> <p>8 Q. I'm sorry. Prolene® mesh.</p> <p>9 A. Correct.</p> <p>10 Q. The other reason that you disagree</p> <p>11 with Dr. Rosenzweig's opinion on that is because</p> <p>12 you, yourself, have seen Prolene® sutures in</p> <p>13 patients of yours that have been there for years,</p> <p>14 if not over a decade, and they weren't oxidized</p> <p>15 or degraded?</p> <p>16 A. So not only Prolene® sutures but</p> <p>17 also Prolene® mesh.</p> <p>18 Q. Used to treat?</p> <p>19 A. Stress incontinence.</p> <p>20 Q. What does it mean for something to</p> <p>21 be cytotoxic? Cytotoxic. Excuse me.</p> <p>22 What does it mean for something to</p> <p>23 be cytotoxic?</p> <p>24 A. My understanding is that it would</p> <p>25 be toxic to cells.</p>	<p style="text-align: right;">Page 88</p> <p>1 million women that have benefited greatly from</p> <p>2 this technology over a period of, you know, over</p> <p>3 17 years, probably more like 20 years at this</p> <p>4 point including Europe, and I think that's sort</p> <p>5 of a ridiculous statement because we just don't</p> <p>6 see that clinically.</p> <p>7 Q. Move to strike after the first</p> <p>8 reference to clinical significance.</p> <p>9 MR. ROSENBLATT: Doctor, you can</p> <p>10 answer however you see fit.</p> <p>11 Q. What condition is the Burch</p> <p>12 procedure designed to treat?</p> <p>13 A. Stress urinary incontinence.</p> <p>14 Q. Do you agree that although the</p> <p>15 Burch procedure may take longer and require a</p> <p>16 short hospitalization, it's a safer procedure</p> <p>17 than synthetic slings?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 A. I disagree with that statement.</p> <p>20 Q. Why?</p> <p>21 A. First of all, I do Burch</p> <p>22 procedures. I've been doing laparoscopic Burch</p> <p>23 procedures since 1993. I think it's a very good</p> <p>24 procedure to treat stress incontinence, but the</p> <p>25 long-term results are not as good as with</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. If a material is cytotoxic, does</p> <p>2 that mean it can cause cell death and</p> <p>3 complications?</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 A. I believe the definition of</p> <p>6 cytotoxicity is death to cells.</p> <p>7 Q. Dr. Rosenzweig opines that</p> <p>8 Ethicon's Prolene® mesh is not suitable for</p> <p>9 permanent implant in women because it's</p> <p>10 cytotoxic. Do you agree with that?</p> <p>11 A. I have not seen any literature that</p> <p>12 would substantiate that claim.</p> <p>13 Q. If there was credible scientific</p> <p>14 evidence that polypropylene is cytotoxic, would</p> <p>15 that render it not suitable for permanent</p> <p>16 implants in women?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 A. No, I think it would have to have</p> <p>19 some clinical significance.</p> <p>20 And again, let's go back and state,</p> <p>21 as I did earlier, that we've been using</p> <p>22 polypropylene and Prolene® sutures for decades,</p> <p>23 and I'm not aware of any untoward effects that</p> <p>24 that might have of any clinical significance, and</p> <p>25 you know, you've got -- you've got several</p>	<p style="text-align: right;">Page 89</p> <p>1 midurethral slings, and you open up a whole host</p> <p>2 of other potential complications that are not</p> <p>3 seen with midurethral slings.</p> <p>4 Q. What are those?</p> <p>5 A. Well, there's, you know, in general</p> <p>6 the risk of general anesthesia. So if you do a</p> <p>7 laparoscopic Burch, you really need to use</p> <p>8 general anesthesia, so that increases the risk</p> <p>9 compared to doing a midurethral sling under local</p> <p>10 anesthesia with conscious sedation.</p> <p>11 Now, you're also getting</p> <p>12 intraperitoneal with a laparoscopic Burch or an</p> <p>13 open Burch, so there's the potential of major</p> <p>14 vascular injury. There's the potential of a</p> <p>15 bowel injury. And although, you know,</p> <p>16 theoretically you could get a bowel injury with a</p> <p>17 midurethral sling, it's exceedingly rare. It's</p> <p>18 an incredibly low number.</p> <p>19 And, you know, any time you do</p> <p>20 general anesthesia and you take longer, there are</p> <p>21 always going to be inherent risks of DVTs and,</p> <p>22 you know, aspiration and et cetera.</p> <p>23 So I think midurethral slings have</p> <p>24 been shown to be a much safer alternative than</p> <p>25 the Burch. That said -- may I continue?</p>

<p style="text-align: right;">Page 90</p> <p>1 Q. Of course.</p> <p>2 A. I'm doing some more of them these</p> <p>3 days just because of all the, again, fear</p> <p>4 mongering, that women come in and have a --</p> <p>5 they're afraid of mesh. And so even after</p> <p>6 talking to them, some women will prefer,</p> <p>7 honestly, to have the old-fashion Burch, which is</p> <p>8 a very good procedure, but I don't think it's as</p> <p>9 good as a midurethral sling.</p> <p>10 Q. Move to strike the reference to</p> <p>11 fear mongering.</p> <p>12 A. I like that.</p> <p>13 Q. Me, not so much.</p> <p>14 The Burch procedure is a very good</p> <p>15 procedure to treat stress urinary incontinence,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. You perform Burch procedures to</p> <p>19 this day, correct?</p> <p>20 A. Correct.</p> <p>21 Q. In fact, you perform more Burch</p> <p>22 procedures now than you use to.</p> <p>23 A. No.</p> <p>24 Q. No?</p> <p>25 A. No. You know, back in 1995 when I</p>	<p style="text-align: right;">Page 92</p> <p>1 them the best treatment possible.</p> <p>2 Although I think a Burch is a good</p> <p>3 procedure, I don't think it's the best treatment</p> <p>4 possible, and I think what we're going to be</p> <p>5 seeing are more patients coming back with</p> <p>6 recurrences of their stress incontinence, and you</p> <p>7 know, I hope that's not the case, but I do know</p> <p>8 it's the case just if you look at the literature.</p> <p>9 Ultimately there is a decrease in the efficacy of</p> <p>10 a Burch procedure over time.</p> <p>11 Q. Over what period of time?</p> <p>12 A. Well, certainly, you know, the</p> <p>13 early studies on comparing Burch with TVT are</p> <p>14 similar, but as you get out to about five years,</p> <p>15 seven years, there's a significant decline, and</p> <p>16 there are studies even going out 15 years that --</p> <p>17 you know, whereas when you do a midurethral</p> <p>18 sling, it's pretty rare for a patient to come</p> <p>19 back and say, you know, that sling worked for a</p> <p>20 couple of years and now it's not working. It</p> <p>21 really is consistent. But with Burchs, I'm</p> <p>22 seeing patients I operated on 20 years ago who</p> <p>23 are coming back saying, yeah, I got that stress</p> <p>24 incontinence again, what can you do for me now?</p> <p>25 Q. Do you agree that if complications</p>
<p style="text-align: right;">Page 91</p> <p>1 first started my practice, that was -- 90 percent</p> <p>2 of my anti-incontinence operations were</p> <p>3 laparoscopic Burch.</p> <p>4 Q. You're performing more Burch</p> <p>5 procedures in recent years than you use to,</p> <p>6 correct?</p> <p>7 A. Slightly more, yes.</p> <p>8 Q. The reason you're performing more</p> <p>9 Burch procedures in recent years is due to fear</p> <p>10 of complications by the general public concerning</p> <p>11 the use of polypropylene mesh slings, true?</p> <p>12 A. No. It's because of patient's</p> <p>13 anxiety seeing ads on TV and what they read in</p> <p>14 the internet about transvaginal mesh, and they</p> <p>15 equate midurethral slings with transvaginal mesh,</p> <p>16 and some women will come in with an attitude,</p> <p>17 please do not talk to me about using any mesh in</p> <p>18 the vagina.</p> <p>19 Q. Does that irritate you when that</p> <p>20 happens?</p> <p>21 A. I think irritate's the wrong word.</p> <p>22 I think -- you know, I'm -- I think it's a shame</p> <p>23 that women have -- you know, that women are being</p> <p>24 exposed to this because first and foremost my</p> <p>25 goal is to take care of my patients and to offer</p>	<p style="text-align: right;">Page 93</p> <p>1 do occur following a Burch procedure they're</p> <p>2 rarely long-term and they're easy to treat?</p> <p>3 A. Well, again, if you consider</p> <p>4 failure, you're talking about a whole another</p> <p>5 operation for their stress incontinence. I've</p> <p>6 seen ureteral injuries. In fact, I've published</p> <p>7 on a ureteral injury after a Burch, where I've</p> <p>8 never seen a ureteral injury after a midurethral</p> <p>9 sling. In fact, I'm not even aware that it's</p> <p>10 ever been -- I'm not sure if it's ever been</p> <p>11 reported, but certainly I've never had that</p> <p>12 experience. But failure is not to be taken</p> <p>13 lightly, and to me, that is a complication</p> <p>14 because it requires the patient undergo another</p> <p>15 operation.</p> <p>16 I've also seen urinary retention</p> <p>17 after a Burch, although, you know, obviously you</p> <p>18 can see that after any anti-incontinent</p> <p>19 operation, but to relieve urinary retention after</p> <p>20 a sling is much easier than to relieve urinary</p> <p>21 retention after a Burch.</p> <p>22 Q. What's the most common complication</p> <p>23 resulting from a Burch procedure?</p> <p>24 A. I would have to say voiding</p> <p>25 dysfunction.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. Is that easy to treat?</p> <p>2 A. Well, sometimes it will manifest --</p> <p>3 it can be treated just with time and with</p> <p>4 catheterization, but occasionally you have to go</p> <p>5 back in and remove the stitches, and that would</p> <p>6 require another general anesthesia, entry into</p> <p>7 the space of Retzius and literally cutting the</p> <p>8 sutures, and I've had to do that a couple times.</p> <p>9 Q. And that's what you would consider</p> <p>10 a complete fail, a complete failure of the Burch</p> <p>11 procedure?</p> <p>12 A. I mean, to me -- in my mind, a</p> <p>13 failure of the Burch is when it doesn't treat the</p> <p>14 stress incontinence which is about 15 percent of</p> <p>15 the time, so. Yeah, about 15 percent of the</p> <p>16 time. As opposed to a failure versus a</p> <p>17 complication. So I look at them differently, you</p> <p>18 know, yeah.</p> <p>19 Q. What percentage of Burch procedure</p> <p>20 patients require another surgery?</p> <p>21 MR. ROSENBLATT: Jeff --</p> <p>22 Q. Strike that. What percentage of</p> <p>23 Burch patients have their procedure fail thus</p> <p>24 requiring another surgery?</p> <p>25 MR. ROSENBLATT: Are we going to</p>	<p style="text-align: right;">Page 96</p> <p>1 to grow with advancing time up to, you know, 15,</p> <p>2 20 years.</p> <p>3 Q. And I understand there's variables</p> <p>4 and there's a range, but if a woman were to peek</p> <p>5 her head in the door right now and say, Doctor,</p> <p>6 I've got stress urinary incontinence, I want to</p> <p>7 undergo a Burch procedure, if it fails typically</p> <p>8 how long after the surgery will it fail?</p> <p>9 A. So it can either be immediate,</p> <p>10 right, because of 85 percent success, and 15</p> <p>11 percent of women will come back and say, you</p> <p>12 know, it just -- it isn't working. I mean, this</p> <p>13 to me, it's like Goldilocks, right. So it's</p> <p>14 either too tight, which puts you into retention.</p> <p>15 Too loose, and you're in the 15 percent that</p> <p>16 have, you know, quote/unquote, failed. Or it's</p> <p>17 just right, which is, you know, the 85 percent</p> <p>18 range. But typically, in my experience, that we</p> <p>19 may see people five years out, seven years out</p> <p>20 who are coming back saying it worked, but you</p> <p>21 know, now I've got stress incontinence again.</p> <p>22 Q. But would it be fair to say the</p> <p>23 majority of women whose Burch procedure fails,</p> <p>24 they know it immediately. You know right away</p> <p>25 you're not the Goldilocks.</p>
<p style="text-align: right;">Page 95</p> <p>1 count this as his TVT general depo as well?</p> <p>2 MR. CRAWFORD: Sure.</p> <p>3 MR. ROSENBLATT: All right.</p> <p>4 A. So what most people will quote in</p> <p>5 the literature is that the success rate, meaning,</p> <p>6 you know, successful treatment of stress</p> <p>7 incontinence, is about 85 percent with a Burch</p> <p>8 whether it's done open or laparoscopic.</p> <p>9 Q. When Burch procedures fail</p> <p>10 completely, typically how long after the surgery</p> <p>11 does that occur?</p> <p>12 A. It's variable. So it can occur</p> <p>13 immediately if you don't tension the sutures</p> <p>14 correctly, and that's really done by surgeon</p> <p>15 judgment. You know, it's a kind of -- Gestalt.</p> <p>16 I don't know how to spell Gestalt. Anyways. But</p> <p>17 over time because we're just dealing with</p> <p>18 sutures, that can tear through.</p> <p>19 And by the way, we are talking</p> <p>20 about permanent sutures, whether they're Prolene®</p> <p>21 or GORE-TEX, but there is a -- you know, if you</p> <p>22 look at like a Kaplan-Meier survival curve. So</p> <p>23 that when you start out with all the patients</p> <p>24 that are successful over time, the survival</p> <p>25 curve, meaning, you know, failure, does continue</p>	<p style="text-align: right;">Page 97</p> <p>1 A. So that is a -- I don't know what</p> <p>2 the breakdown would be, but that can happen, but</p> <p>3 I've also seen women who after a year or two or</p> <p>4 three come back with complaints of symptoms, and</p> <p>5 I think it has to do with not just the way the</p> <p>6 procedure is performed, but it has to do with the</p> <p>7 patient's lifestyle, if she's a woman who has</p> <p>8 chronically increased intra-abdominal pressure,</p> <p>9 she's an asthmatic, she's a nurse and she lifts</p> <p>10 patients, she goes to the gym a lot, she's</p> <p>11 constipated. You know, there are lifestyle</p> <p>12 issues that can affect the long-term success, so</p> <p>13 it is very variable.</p> <p>14 Q. Do you agree with Dr. Rosenzweig</p> <p>15 that polypropylene is chemically reactive and not</p> <p>16 inert?</p> <p>17 A. I do disagree with that.</p> <p>18 Q. Why?</p> <p>19 A. I think most -- the literature that</p> <p>20 I've read, quality of literature, suggests that</p> <p>21 polypropylene is for all intents and purposes</p> <p>22 biologically inert.</p> <p>23 Q. What quality literature are you</p> <p>24 referring to?</p> <p>25 A. I've read a number of studies about</p>

<p style="text-align: right;">Page 98</p> <p>1 polypropylene or Prolene® mesh. I can't quote 2 for you the names, but that discuss the fact that 3 it is biologically inert, and also, in the 4 clinical literature, it is referred to as 5 biologically inert, and I've never seen anything 6 either in literature or in my personal experience 7 that suggests that it's not inert.</p> <p>8 Q. I'm really interested to see what 9 quality literature you're referring to that shows 10 that it's inert. Can we look that up on the next 11 break?</p> <p>12 A. Yes.</p> <p>13 Q. What does inert mean?</p> <p>14 A. Non-immunogenic.</p> <p>15 Q. What does non-immunogenic mean?</p> <p>16 A. Doesn't elicit an immune response of 17 any clinical significance from the host.</p> <p>18 Q. In layman's terms, does that mean 19 the body doesn't attack it?</p> <p>20 A. Not really. I mean, you know, we 21 talked about foreign body response, but it isn't 22 seen as something that you could -- like a kidney 23 transplant, you know, something that you would 24 develop a severe immune response to that would 25 elicit a severe immune response, basically.</p>	<p style="text-align: right;">Page 100</p> <p>1 artifact of the preparation of the material, and 2 that if you do a proper washing of that, you'll 3 seen pristine polypropylene without any evidence 4 of degradation or oxidation. And in addition, 5 you know, with the mesh that we're talking about 6 here, which is Prolene®, has additives that are 7 antioxidants.</p> <p>8 Q. Are you aware of any literature 9 that indicates polypropylene mesh can oxidize 10 inside the vagina, thus causing mesh to degrade 11 and crack and break apart?</p> <p>12 A. So I have seen literature, but 13 there seems to be two schools of thought, and 14 the, quote/unquote, artifacts that I've seen with 15 scanning electron microscopy, appear to be just 16 that, where it's not the cracking of the 17 polypropylene material but of a biofilm that is 18 on top of the polypropylene.</p> <p>19 Q. To be clear, you have seen 20 literature that indicates polypropylene mesh can 21 oxidize inside the vagina, thus creating or thus 22 causing it to degrade, crack and break apart?</p> <p>23 MR. ROSENBLATT: Object to the 24 form.</p> <p>25 A. The literature I've seen is</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. Do you agree with Dr. Rosenzweig 2 that polypropylene can degrade and release toxic 3 compounds into pelvic tissues?</p> <p>4 A. No, I don't agree with that.</p> <p>5 Q. Why not?</p> <p>6 A. Well, I've never seen any evidence 7 that there's any clinical significance that there 8 are any toxins released. I'm not aware of any 9 literature that I've reviewed that suggests that.</p> <p>10 Q. I think we may have touched on this 11 already, but it will only take a second.</p> <p>12 Do you agree with Dr. Rosenzweig 13 that polypropylene mesh can oxidize inside the 14 vagina thus causing the mesh to degrade, crack 15 and break apart?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 A. So are we talking about 18 polypropylene or Prolene®, first?</p> <p>19 Q. Polypropylene.</p> <p>20 A. So I have not seen evidence of 21 that, and I've read the literature, you know, the 22 biochemistry, as we've discussed, some people 23 suggesting that there's cracking, surface 24 cracking, but other excellent evidence that I've 25 seen that shows that that's a biofilm, that's an</p>	<p style="text-align: right;">Page 101</p> <p>1 interpretation of scanning electron microscopy 2 but not that proves that degradation or cracking 3 exists.</p> <p>4 Q. Are you aware of any changes 5 Ethicon has made to Prolene® mesh since it was 6 introduced to the market?</p> <p>7 A. Are we talking about Prolene® 8 suture or Prolene® mesh?</p> <p>9 Q. Mesh.</p> <p>10 A. The only thing that I'm aware of is 11 the way that it's, the Prolene® mesh, is cut.</p> <p>12 Q. What change was made?</p> <p>13 A. Well, it was being offered 14 initially as mechanically cut, and then it was 15 being offered both as mechanically -- mechanical 16 or laser cut. I'm not aware of any other 17 changes.</p> <p>18 Q. Which came first, mechanically cut 19 mesh or laser cut mesh?</p> <p>20 A. I believe mechanically cut.</p> <p>21 Q. Do you know why they started making 22 it laser cut as opposed to mechanically cut?</p> <p>23 A. I believe it was -- it simplified 24 the manufacturing process, I believe. I believe 25 I heard that.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. Are you aware of any reasons why 2 Ethicon began to cut its polypropylene mesh using 3 lasers, as opposed to mechanically, other than 4 because it simplified the manufacturing process? 5 A. No, I'm not aware. 6 Q. You've never heard it said that 7 laser cut polypropylene mesh is safer than 8 mechanically cut polypropylene mesh? 9 A. No. 10 Q. You never heard it said that 11 laser -- there's less complications with the use 12 of laser cut mesh as opposed to mechanically cut 13 mesh? 14 A. No. You know, that may have been 15 said by a plaintiff expert opinion, but you know, 16 I've had experience with both. I can tell you 17 from my personal experience I've not noticed any 18 difference, and I haven't had, you know, any 19 change in complications going from one type of 20 cut to another. Nor am I aware of any literature 21 that shows there's a difference. 22 Q. Is another way of saying that 23 you're unaware of any clinical difference between 24 the use of mechanically cut mesh and laser cut 25 mesh?</p>	<p style="text-align: right;">Page 104</p> <p>1 an animal study. 2 Q. Move to strike after "don't recall 3 seeing that." 4 Are you aware of a 2009 5 presentation in which Ethicon Medical Director 6 Piet Hinoul stated that meshes are not 7 biologically inert? 8 MR. ROSENBLATT: Object to form. 9 A. I may have seen something to that 10 effect, but I don't agree with that. And are we 11 talking about in humans or in animals? 12 Q. Have you ever opened an Ethicon 13 mesh product and found that synthetic mesh inside 14 is broken, cracked or brittle? 15 A. No. 16 Q. Doctor, I'm referring to 17 Exhibit No. 2, specifically page 43 of 18 Dr. Rosenzweig's report, and this particular page 19 bears two images of what appear to be blue mesh. 20 Do you see those? 21 A. Yes. 22 MR. ROSENBLATT: And this is 23 Rosenzweig's TVT report? 24 MR. CRAWFORD: Yes, it is. 25 Do those images appear to reveal</p>
<p style="text-align: right;">Page 103</p> <p>1 A. Correct. 2 Q. Are you aware of any internal 3 studies performed by Ethicon in which scientists 4 working for Ethicon concluded that Prolene® can 5 degrade while implanted in the human body? 6 MR. ROSENBLATT: Object to form. 7 A. I am not aware of any such studies. 8 Is that the word you used? 9 Q. Yes, sir. 10 A. No. 11 Q. You're unfamiliar with a study in 12 1987 where Ethicon scientists found that Prolene® 13 degrades? 14 MR. ROSENBLATT: Object to form. 15 A. I have not seen that study. 16 MR. ROSENBLATT: Do you want to 17 show it to him to see if he's seen it? 18 Q. Do you know whether Ethicon was 19 advised by an outside consulting group in June of 20 2011 that an animal study showed polypropylene 21 can degrade following an implant? 22 A. Did you say an animal study? 23 Q. Yes, sir. 24 A. I don't recall seeing that, but I'm 25 not sure what significance that has coming from</p>	<p style="text-align: right;">Page 105</p> <p>1 particles of the mesh that have begun to break 2 off inside the package. 3 MR. ROSENBLATT: Object to form. 4 Lack of foundation. 5 A. So I don't know what you mean by 6 broken off, but it looks like there are small 7 pieces of polypropylene fibers that are separate 8 from the body of the mesh. 9 Q. Have you ever opened an Ethicon 10 product and seen mesh that looks like that? 11 A. I don't recall ever seeing that, 12 but if I did see that, that wouldn't bother me at 13 all. 14 MR. CRAWFORD: Move to strike after 15 I don't believe I've ever seen that. 16 Well, let me ask you, if you were 17 to open a package of Ethicon mesh and it were to 18 look at that, would that bother you? 19 A. Not at all. 20 Q. Why? 21 A. We leave sutures in people's 22 bodies, permanent sutures, all the time. We've 23 done it for decades. We leave surgical metal 24 clips in people's bodies all the time. There's 25 no evidence that I'm aware of that small pieces</p>

<p style="text-align: right;">Page 106</p> <p>1 of suture, basically that's what that is, would 2 cause any untoward effects. 3 So to me that looks like an 4 artifact of the cutting process, that when you 5 cut it either -- I don't know if that's laser or 6 mechanical, but there will be little pieces of 7 suture that may be inside the body. Obviously, 8 those pieces have fallen off, and they're not 9 going to be implanted. But even if a mesh did 10 that and little pieces came off, it would be 11 inconsequential. That wouldn't affect anything. 12 Q. 100 percent of the time? 13 A. 100 percent of the time. 14 Q. All right. Did you say there's 15 been other operative procedures where you've left 16 things, foreign bodies, in people's body? 17 A. Yes. Not me, every surgeon. 18 Q. What kind of stuff? 19 A. Surgical titanium clips, float 20 rings, which are, you know, for tubal ligation, 21 sutures. That's a part of doing surgery. 22 Q. And you've never heard of anyone -- 23 you've never heard of an instance where a surgeon 24 has inadvertently left a foreign body in someone 25 after a surgery and it caused horrible</p>	<p style="text-align: right;">Page 108</p> <p>1 clips inadvertently left in someone's body and 2 there be no consequence? 3 A. When you say inadvertently, you're 4 saying not on purpose. 5 Q. Yes, sir. 6 A. Oh, that's not what I'm talking 7 about. I'm talking about clips for bleeding. So 8 they're not inadvertently. They're done on 9 purpose. But they're left. And if you take a 10 x-ray of countless women, you'll see little metal 11 clips throughout their body. You know, that's a 12 common occurrence. And most surgeons don't even 13 tell their patients that they have these clips in 14 them. That's just sort of a -- you know, that 15 goes along with having surgery. Excuse me, one 16 second. Okay. And, you know, I've not seen that 17 cause any untoward effect. 18 Q. Hypothetically speaking, if there 19 were credible scientific evidence that Ethicon 20 Prolene® mesh degrades in the human body, would 21 that make it unsuitable as a permanent implant 22 for stress urinary incontinence? 23 MR. ROSENBLATT: Object to form. 24 A. I guess, again, you'd have to look 25 at, you know, whether it's clinically</p>
<p style="text-align: right;">Page 107</p> <p>1 complications? 2 A. I didn't see that. I mean, you 3 wouldn't like to leave like a clamp inside 4 someone's body. You wouldn't want to leave a 5 sponge inside a body or a retractor. All those 6 things have been left in people's bodies. But 7 things that we just talk about like suture that 8 are covered inside the vagina or inside the body 9 are inconsequential. 10 Q. 100 percent of the time? 11 A. Well, I just gave you an example of 12 things that you wouldn't want to leave inside the 13 body, but I don't see any issue with a piece of 14 mesh or, I'm sorry, a piece of suture of that 15 magnitude causing any problems. I've never ever 16 seen that in 20, 21 years of practice. 17 Q. How many times over the course of 18 your practice have you seen a suture 19 inadvertently left in someone's body following a 20 surgery? Not a suture. What else did you say 21 was inconsequential? You likened the suture 22 to -- 23 A. Clips. 24 Q. Clips. Thank you. How many times 25 over the course of your career have you seen</p>	<p style="text-align: right;">Page 109</p> <p>1 significant. In other words, let's say you used 2 absorbable material for a sling, like, you know, 3 polyglactin. That is meant to degrade. It's 4 meant to be hydrolyzed and get absorbed. But if 5 the woman were continent afterwards, it would be 6 inconsequential. But, you know, I've not seen 7 evidence of degradation of the Prolene® mesh, but 8 if it did degrade but it wasn't clinically 9 significant, it wouldn't matter. 10 Q. If Ethicon became aware of credible 11 scientific evidence that polypropylene has the 12 potential to degrade, would you, as a practicing 13 physician, expect them to conduct relevant 14 testing to determine if naturally occurring 15 conditions in the vagina could cause 16 polypropylene degradation? 17 MR. ROSENBLATT: Object to form. 18 A. I guess it would have to be -- 19 there would have to be some clinical significance 20 associated with it. It would have to -- to me it 21 would have to cause some harm to the patient, and 22 without that, it would be inconsequential. 23 Q. A recurring theme that I'm hearing 24 and correct me if I am wrong, but a recurring 25 theme I keep hearing in your testimony is that it</p>

<p style="text-align: right;">Page 110</p> <p>1 doesn't matter if the polypropylene degrades 2 inside the human body if there's no symptoms due 3 to it. Is that fair?</p> <p>4 MR. ROSENBLATT: Object to form. 5 Misstates the testimony and assumes that 6 degradation does occur.</p> <p>7 A. Well, I was actually going to say 8 exactly that which is, you know, I don't see any 9 credible scientific evidence that there is any 10 degradation of Prolene®. And again, which we 11 have already talked about, Prolene® mesh is just 12 made up of Prolene® fibers that have been woven 13 together, and we have literally a half a century 14 or more of data and clinical experience with 15 Prolene®. So I'm very comfortable that it 16 doesn't degrade. But there would have to be some 17 clinical significance for it to be reportable to 18 physicians. And, you know, what we've seen with 19 TVT slings is an operation that is better than 20 any other operation known to mankind in the 21 history of man -- in the history of women for 22 treating stress incontinence. There is nothing 23 better. It has revolutionized the field of 24 urogynecology, that's a fact. And our world 25 changed in 1999 or 1998 in the United States when</p>	<p style="text-align: right;">Page 112</p> <p>1 even the smaller interstices are large enough to 2 allow macrophages to get in between where 3 bacteria potentially are, and that's evidenced by 4 the fact that we don't see infections, you know, 5 we don't see -- we don't commonly see infections 6 in this mesh even when it's placed 7 transvaginally.</p> <p>8 Q. Does bacteria that's caught up in 9 transvaginal placed pelvic mesh secrete a slimy 10 biofilm that serves to protect and shield the 11 bacteria from destruction by white blood cells?</p> <p>12 MR. ROSENBLATT: Object to form. 13 A. I don't know if that's a -- I 14 actually -- I'm actually not sure where the 15 biofilm comes from, if that's secreted by 16 bacteria or it's from the host response, yeah.</p> <p>17 Q. Following the placement of 18 transvaginally placed pelvic mesh, does there 19 appear a slimy biofilm that serves to shield the 20 bacteria from destruction by white blood cells?</p> <p>21 MR. ROSENBLATT: Object to form. 22 A. I think it's been shown that there 23 can be a biofilm. I don't know if that happens 24 all the time. And, you know, again, we have to 25 come back to it being -- whether or not it's</p>
<p style="text-align: right;">Page 111</p> <p>1 that technology came here, and I'm not being -- 2 I'm not speaking with hyperbole. That was one of 3 the greatest things that have happened in the 4 field of urogynecology for our patients. So I 5 don't see any evidence of there being a problem 6 with it.</p> <p>7 MR. CRAWFORD: Objection as 8 non-responsive and move to strike. 9 Is there a difference between pores 10 in the mesh and interstices?</p> <p>11 A. There is. Pores usually refer to 12 the large holes, for lack of a better word, that 13 you can see with the naked eye, where interstices 14 refers to the smaller holes within the weaving of 15 mesh.</p> <p>16 Q. Does the weave of Ethicon's 17 Prolene® mesh produce very small interstices that 18 allow bacteria to enter and hide from the natural 19 body defenses that are designed to eliminate 20 them?</p> <p>21 MR. ROSENBLATT: Object to form. 22 Lack of foundation. 23 A. Yeah, fortunately -- no, it's not 24 true, in that, and I think it is because of the 25 fact that polypropylene is a monofilament, that</p>	<p style="text-align: right;">Page 113</p> <p>1 clinically significant, and for someone who has 2 placed over 2,000 slings, and I've only had one 3 serious infection, I think Prolene® mesh is 4 incredibly resistant to infection.</p> <p>5 MR. CRAWFORD: Objection as 6 non-responsive. Move to strike everything after 7 "happens all the time." 8 Does the biofilm that surrounds the 9 pelvic -- strike that. 10 Does the biofilm that surrounds the 11 transvaginally placed pelvic mesh increase the 12 foreign body reaction?</p> <p>13 MR. ROSENBLATT: Object to form. 14 Lack of foundation. 15 A. I am not aware of that. 16 Q. Can you say one way or the other 17 whether it does? 18 A. No. 19 Q. Do you agree with Dr. Rosenzweig 20 when he says fibrotic bridging occurs when the 21 fiber surrounding the mesh -- strike that. 22 Do you agree with Dr. Rosenzweig 23 when he says the fibrotic bridging occurs -- God 24 dang. It's getting later. Strike it. 25 Do you agree with Dr. Rosenzweig</p>

<p style="text-align: right;">Page 114</p> <p>1 when he says fibrotic bridging occurs when the 2 fibers surrounding the pores of the mesh are too 3 close together to allow the tissue in the pore 4 space enough room to recover from the trauma of 5 tissue damage due to implanting a surgical 6 prosthetic device?</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 A. I'm not actually sure what he's 9 referring to because there -- though I'm very 10 familiar with the concept of fibrotic bridging, I 11 haven't heard of that being an explanation of 12 recovering from the inflammation. I just haven't 13 heard that argument, nor have I seen that, you 14 know, clinically.</p> <p>15 Q. Dr. Rosenzweig opines that small 16 mesh pores that cause fibrotic bridging turn the 17 mesh into a solid sheet of scar tissue, then 18 there's no room for the tissue to grow into the 19 mesh. Do you agree with that?</p> <p>20 A. I don't agree with that.</p> <p>21 Q. Why not?</p> <p>22 A. Well, if the mesh is placed 23 correctly, which is in a tension-free fashion, 24 there's plenty of space between the pores to 25 prevent fibrotic bridging.</p>	<p style="text-align: right;">Page 116</p> <p>1 contracted or shrank inside their body?</p> <p>2 A. So no. I have seen patients who 3 have come in where -- in patients who have had 4 mesh placed with someone else where it seemed 5 like the mesh had a smaller surface area than 6 what you'd expect to see. But there are a couple 7 of issues there. One is that mesh does not 8 shrink. There's no contractile elements within a 9 mesh. The body reacts to surgery and could react 10 around a mesh to contract, that's why even native 11 tissue repairs you get some vaginal 12 foreshortening and you get vaginal scarring, 13 that's a natural occurrence. And if the mesh 14 happens to be there, it will take up less space. 15 But what I've experienced would be, you know, 16 with hundreds and hundreds of transvaginal 17 meshes, is that there's no clinically significant 18 shrinkage that occurs when a mesh is placed 19 correctly.</p> <p>20 Q. Since you are of the opinion that 21 mesh does not shrink, am I safe to assume you 22 dispute that shrinkage was known by Ethicon as 23 early as 1998 in published works by Ethicon's 24 many consultants, Uwe Klinge and Bernd 25 Klosterhalfen?</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Have you ever seen a video of 2 Ethicon consultant Todd Heniford saying, quote, 3 there's no excuse for using heavy weight, small 4 pore meshes in the human body, closed quote?</p> <p>5 MR. ROSENBLATT: Object to form, 6 lack of foundation.</p> <p>7 A. I have not seen that video, but I 8 can't imagine why that would ever have any 9 relevance to what we're talking about and the 10 types of meshes that we're talking about today.</p> <p>11 MR. ROSENBLATT: Just so you know, 12 Jeff, that video was not any of Ethicon's meshes.</p> <p>13 MR. CRAWFORD: I'll object as 14 non-responsive and move to strike after "have not 15 seen it."</p> <p>16 Thanks, Paul.</p> <p>17 Do you agree with Dr. Rosenzweig 18 that polypropylene mesh is known to contract or 19 shrink once it's put into the human body?</p> <p>20 MR. ROSENBLATT: Object to form.</p> <p>21 A. So in my experience, I have not 22 seen that clinically in my patients.</p> <p>23 Q. To be clear, you've never once in 24 all of your years of clinical practice seen a 25 patient where their polypropylene mesh had</p>	<p style="text-align: right;">Page 117</p> <p>1 A. So I am aware of that, and I have 2 seen those reports, but the first part of your 3 statement was that I don't believe that mesh 4 shrinks, and mesh does not shrink. There's no 5 such thing as mesh shrinking. It's not like you 6 put it in a dryer like, you know, a shirt in a 7 dryer and it gets smaller. It's the fibrosis 8 that occurs as a natural healing process of 9 surgery that causes shrinkage. Because as I 10 said, native tissue repairs you can get stenosis 11 of the vagina, you can get foreshortening of the 12 vagina. Mesh does not shrink. So if there is 13 any decrease in the surface area of the mesh, 14 it's not from the mesh itself. It's the tissue 15 around the mesh.</p> <p>16 MR. CRAWFORD: Object and move to 17 strike the non-responsive portions of that 18 answer.</p> <p>19 You are familiar with the Klinge 20 and the Klosterhalfen study.</p> <p>21 A. Yes.</p> <p>22 Q. And you're aware that they noted in 23 their paper that polypropylene mesh shrinks 30 to 24 50 percent; is that right?</p> <p>25 MR. ROSENBLATT: Object to form.</p>

<p style="text-align: right;">Page 118</p> <p>1 If you have the paper and you want to put it in 2 front of him, he can take a look at it.</p> <p>3 A. Yeah, I was about to say I'd like 4 to see the paper 'cause I want to see if that was 5 from an animal study. I am familiar with the 6 so-called, you know, quote/unquote, shrinkage or 7 contracture in hernia meshes, but I'm almost 8 familiar with literature -- the one that comes to 9 mind is Dietz -- I think it's D-E-I-T-Z or 10 D-I-E-T-Z -- that shows using ultrasound that 11 there is no shrinkage of mesh implanted in 12 humans. So I think that is debatable and 13 controversial.</p> <p>14 Q. Do you agree that if there is 15 credible scientific evidence that polypropylene 16 mesh shrinks 30 to 50 percent and as a result 17 there's an adverse clinical effect on the 18 patient, then it's not suitable for its intended 19 application as a permanent prosthetic implant in 20 women?</p> <p>21 MR. ROSENBLATT: Object to form. 22 Lack of foundation, compound.</p> <p>23 A. What you're suggesting is not the 24 case. You know, and the reason I say that and 25 I'm comfortable saying that is I've been</p>	<p style="text-align: right;">Page 120</p> <p>1 MR. ROSENBLATT: Object to form. 2 Compound, incomplete hypothetical.</p> <p>3 A. So I think that you said if there 4 is credible scientific evidence. I'd want to 5 weigh all the evidence, right. I mean, so you 6 can't cherry pick, and what I mean by that is 7 just -- you know, like, for instance, when I 8 started, and don't object to this, please, but 9 when I started -- hear me out.</p> <p>10 When I started doing this work for 11 Butler Snow, I asked them to send me all -- you 12 know, I did my own searches, PubMed search, but 13 they have pretty good resources, too, and I said 14 send me the literature, the good and the bad. 15 Send me the literature that -- for instance, in 16 this topic, this particular topic, if there's 17 literature that shows that there's no shrinkage, 18 like the Dietz article, I want to see the 19 literature that seems to suggest there is 20 shrinkage, and I want to evaluate it. I looked 21 at all of it. I didn't cherry pick to say, okay, 22 that article supports my theory and that's all 23 I'm going to look at. I looked at it all. So 24 there may be an article out there that you're 25 referring to, and I'd be happy to see it, that</p>
<p style="text-align: right;">Page 119</p> <p>1 implanting mesh transvaginally for 15 years, and 2 I do not see that clinically.</p> <p>3 Could a particular woman have a 4 fibrotic reaction where she would have had a 5 fibrotic reaction and scarring with a native 6 tissue repair? Yeah, that can happen, and there 7 might be mesh there, but I do not see that -- 8 when you say, you know, if you could show that 9 mesh -- mesh does not shrink. So it doesn't make 10 a lot of sense to me to assume that, you know, 11 mesh shrinks 'cause it doesn't shrink.</p> <p>12 MR. CRAWFORD: Objection. 13 Non-responsive, move to strike.</p> <p>14 I understand that you've opined 15 mesh doesn't shrink. I'm asking you a 16 hypothetical question, and I'll pose a 17 hypothetical question to you.</p> <p>18 If there's -- strike it.</p> <p>19 Hypothetically speaking if there's 20 credible scientific evidence that polypropylene 21 mesh shrinks 30 to 50 percent in the human body 22 and that shrinkage results in a clinically 23 adverse effect upon the patient, then it's not 24 suitable for application as a permanent 25 prosthetic implant in a woman.</p>	<p style="text-align: right;">Page 121</p> <p>1 suggests that mesh shrinks, but I would want to 2 look at all the data. And if the preponderance 3 of data show that mesh shrinks, then I would have 4 a different opinion, but I don't.</p> <p>5 MR. CRAWFORD: Objection. 6 Non-responsive, move to strike.</p> <p>7 MR. ROSENBLATT: Want to take 8 another quick break?</p> <p>9 MR. CRAWFORD: Yeah. 10 (A break was taken.)</p> <p>11 BY MR. CRAWFORD: 12 Q. Dr. Rosenzweig has opined that in 13 addition to fraying and particle loss 14 mechanically cut synthetic polypropylene mesh has 15 been shown to rope, curl and deform when it's 16 under tension. Do you have an opinion on that?</p> <p>17 A. So maybe I missed the first part of 18 this. Which mesh are we talking about?</p> <p>19 Q. Let's go with Prolene® mesh. 20 A. Prolene®. So I do have an opinion 21 on that and that is under normal clinical 22 conditions you would never put Prolene® mesh, 23 like in TVT or any of those products, under that 24 kind of tension that would cause roping or 25 curling.</p>

<p style="text-align: right;">Page 122</p> <p>1 If you take a piece of Prolene®</p> <p>2 sling mesh and pull it really hard, it will turn</p> <p>3 into a cord, no question about it. You would</p> <p>4 never ever do that clinically. It just -- it</p> <p>5 doesn't make any sense. So whether that happens</p> <p>6 in a bench or you do that in a cadaver, it's</p> <p>7 clinically insignificant.</p> <p>8 Q. To summarize your testimony, it</p> <p>9 doesn't matter whether Prolene® mesh frays or has</p> <p>10 particle loss and has been shown to rope, curl</p> <p>11 and deform when it's under tension because in</p> <p>12 real-life situations it's never going to be under</p> <p>13 that kind of tension; is that fair?</p> <p>14 MR. ROSENBLATT: Object to form.</p> <p>15 A. Not if it's done using the</p> <p>16 instructions for use the way peer to peer,</p> <p>17 surgeon to surgeons teach how to perform a</p> <p>18 procedure, that is not clinically relevant.</p> <p>19 Q. Dr. Rosenzweig has opined that</p> <p>20 characteristics of Ethicon's mesh including</p> <p>21 particle loss, fraying, roping and curling make</p> <p>22 it improper for use in the vaginal canal. Do you</p> <p>23 agree with that?</p> <p>24 A. So, again, you mentioned mesh, and</p> <p>25 just so I know which mesh we're talking about --</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Yes, it's possible that if you pull</p> <p>2 on mesh, which you shouldn't do because -- and</p> <p>3 it's not just in the instructions, but you know,</p> <p>4 this is how it's taught, is that you leave these</p> <p>5 meshes, whether it's prolapse mesh or sling mesh</p> <p>6 for stress incontinence, in a tension-free</p> <p>7 manner, then you don't get that reduction in pore</p> <p>8 size, and you get good -- excellent tissue</p> <p>9 ingrowth.</p> <p>10 MR. CRAWFORD: Objection.</p> <p>11 Non-responsive, move to strike.</p> <p>12 I'm just going to ask you a</p> <p>13 yes-or-no question.</p> <p>14 Do you agree that roping or curling</p> <p>15 of the mesh, that is the synthetic polypropylene</p> <p>16 transvaginal mesh, can lead to a loss of pore</p> <p>17 size?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 Asked and answered, broad.</p> <p>20 A. And I can't answer that yes or no</p> <p>21 without saying that's clinically irrelevant</p> <p>22 because you would never pull on it like that, but</p> <p>23 obviously, if you pull on mesh inappropriately,</p> <p>24 you will reduce the pore size, depending on the</p> <p>25 configuration of the mesh.</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Prolene®.</p> <p>2 A. Prolene® mesh like in TVT?</p> <p>3 Q. Yes, sir.</p> <p>4 A. I disagree with it because I think</p> <p>5 it's completely appropriate for use in the</p> <p>6 vagina, and that's been borne out after millions</p> <p>7 of cases.</p> <p>8 Q. Do you agree that particle loss and</p> <p>9 fraying of synthetic mesh can lead to an</p> <p>10 increased inflammatory response?</p> <p>11 MR. ROSENBLATT: Object to form.</p> <p>12 A. Again, maybe I'm missing the point,</p> <p>13 but I think it's my same answer, which is that</p> <p>14 under normal conditions you would never pull mesh</p> <p>15 tight enough to cause roping or fraying, and so</p> <p>16 it's sort of irrelevant. But even if you did</p> <p>17 have particle loss, those particles are</p> <p>18 inconsequential clinically.</p> <p>19 MR. CRAWFORD: Objection as</p> <p>20 non-responsive. Move to strike everything other</p> <p>21 than "if you did have particles" and thereafter.</p> <p>22 If synthetic polypropylene mesh</p> <p>23 were to rope or curl, would that lead to a loss</p> <p>24 of pore size?</p> <p>25 MR. ROSENBLATT: Object to form.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. If a certain amount of tension is</p> <p>2 put on synthetic polypropylene mesh, can that</p> <p>3 lead to a loss of pore size.</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 A. If you put inappropriate tension on</p> <p>6 a mesh, depending on the configuration of the</p> <p>7 mesh, the way it's woven, it can lead to a</p> <p>8 decrease in pore size, that is correct.</p> <p>9 Q. I think attached to your report,</p> <p>10 which is Exhibit No. 1, there's a reliance list.</p> <p>11 Can you pull that out?</p> <p>12 A. This one doesn't have it.</p> <p>13 Q. I know I have it in here somewhere.</p> <p>14 Were you able to get your hands on</p> <p>15 your reliance list?</p> <p>16 A. Yes.</p> <p>17 Q. What is this? What does this list</p> <p>18 represent?</p> <p>19 A. This list represents all the</p> <p>20 documents and medical literature and other</p> <p>21 materials that I have relied on for my opinions</p> <p>22 in my report.</p> <p>23 Q. Should someone who is considering</p> <p>24 your report look at this reliance list and assume</p> <p>25 that before you wrote your report that you</p>

<p style="text-align: right;">Page 126</p> <p>1 submitted in this case you sat down and read each 2 and every single one of these documents and 3 watched every single one of these videos in 4 conjunction with writing your report? 5 MR. ROSENBLATT: Object to form. 6 A. So many of these articles I've been 7 reading about for the last 15 years. There were 8 some materials in this reliance report that were 9 documents that I scanned that I didn't read every 10 word. There's no way I could have. And there 11 were articles where I scanned but I read the 12 abstracts, but yes, this is all the material 13 that's in there, and I went through it to come up 14 with my opinions. 15 Q. Turn to the -- shoot, I don't know 16 what page this is. Man, I wish this had page 17 numbers on it. 18 A. Good point. 19 Q. I'll start from the back. Flip, 20 one, two, three, four pages, and there will be a 21 list that's got a bunch of videos. It's going to 22 be on this side, I believe. Yeah, right here. 23 A. Okay. 24 Q. There's a list of videos that 25 begins with ETH.MESH.PM.000001, Prolift</p>	<p style="text-align: right;">Page 128</p> <p>1 A. Oh, it could have been years ago. 2 Q. As long as ten years back? 3 A. It might have been. It might have 4 been five years. 5 Q. Turn to the last page, please. 6 Actually, it's going to be the second-to-last 7 page. I've counted 30 notations of deposition 8 testimony. Does that look about right? 9 A. Yes. 10 Q. Okay. Do those represent -- does 11 each one of those represent an entire deposition 12 transcript? 13 A. I believe so. 14 Q. Okay. So there's -- we know 15 there's 30 deposition transcripts that you've 16 read front to back in preparation for drafting 17 your report in this case? 18 A. I scanned some of these. You know, 19 just kind of like going in looking for words that 20 I, you know, cared about. Did I read them word 21 for word, no, no. There was not enough time to 22 do that. 23 Q. Yeah, that's kind of what I was 24 thinking? 25 A. Yeah. It's a lot.</p>
<p style="text-align: right;">Page 127</p> <p>1 Professional Education Videos. Do you see that? 2 A. Yes. 3 Q. I have counted 33 videos in that 4 list. Do you have any reason to dispute that's 5 about how many there were there? 6 A. No, I will take your word for it. 7 Q. When was the last time you watched 8 any of those videos? 9 A. I don't remember exactly when, but 10 some of these videos I had seen in the past and 11 was familiar with them, but you know, what I did 12 with these videos is, and I couldn't tell you 13 which one is which, but I would take the cursor 14 and move along and just familiarize myself with 15 the videos. 16 Q. Okay. When's the last time you did 17 that with any of these videos? 18 A. Probably two weeks ago. 19 Q. And did you do that with all the 20 videos? 21 A. If they're listed there, yeah. I 22 don't remember exactly when. Some of them I may 23 have seen a long time ago, but I remember videos. 24 Q. When you say a long time ago, how 25 long are we talking?</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. It is a lot. Where did you obtain 2 all the deposition testimony that's listed in 3 your reliance list? 4 A. From counsel. 5 Q. From the attorneys representing 6 Ethicon in this case? 7 A. Yes. 8 Q. When you received deposition 9 testimony from the attorneys working for Ethicon, 10 did you get entire deposition transcripts, or did 11 you just get excerpts, certain pieces of the 12 testimony? 13 A. I would have to look. I don't know 14 for sure. I assume they were all complete. I 15 assume they were all complete. 16 Q. Well -- 17 A. I can't tell you for sure. 18 Q. -- you just got involved in this 19 case about three months ago. 20 A. That's right. 21 Q. Can you remember back about three 22 months to tell us whether or not you received 23 from Ethicon's attorneys full transcripts of 24 these depositions or just excerpts? 25 A. So when I would get a transcript --</p>

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1 just let me answer it this way -- you know, it's
 2 usually like four pages on a page, right? And I
 3 wouldn't check the page number. I would just
 4 kind of scan. So I'm not paying attention to the
 5 actual page number, but I'm just scanning it to
 6 see what's important to me. Did I read word for
 7 word? No, I couldn't have. But no, it didn't
 8 seem -- to me, it did not seem ever that it was,
 9 like, okay, cherry picking, this is a good thing
 10 for you to read. No, it was the transcript, I
 11 believe.

12 MR. CRAWFORD: Objection.
 13 Non-responsive to the cherry picking part.

14 When you received deposition
 15 testimony from the attorneys for Ethicon, was it
 16 highlighted.

17 A. No.

18 Q. Having reviewed the deposition
 19 testimony that's listed on your reliance list,
 20 did you then ask for additional testimony from
 21 any of these witnesses?

22 A. I didn't know that there was
 23 additional testimony, if there was any.

24 Q. Did you read any of these
 25 deposition excerpts and request -- and say, "Hey,

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1 I need to learn a little bit more about what was
 2 said in this deposition. Do you have A, B or C?"
 3 Did that ever happen?

4 A. So I object because you used the
 5 word "excerpt," and I don't think that we decided
 6 that there were excerpts.

7 Q. Objection overruled.

8 A. But, no, I did not request anything
 9 else.

10 MR. ROSENBLATT: He's doing my job
 11 for me.

12 Q. To clarify, this reliance list
 13 includes articles, literature, videos and a
 14 variety of other documents and materials that
 15 relate to issues in this case that you have seen
 16 or reviewed over the course of your career --

17 A. Correct.

18 Q. -- going years back?

19 A. Correct.

20 Q. These are not -- strike that.

21 This is not a list of materials and
 22 documents that you have reviewed in their
 23 entirety since becoming involved in this case in
 24 March or April of 2016?

25 MR. ROSENBLATT: Object to form.

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1 A. I agree to an extent in that, as
 2 you mentioned, many of these go back many years,
 3 and that's what I do, right? I mean, I review
 4 literature on a weekly basis. I mean, there are
 5 always new studies that come out. But I thought
 6 it would be important to list the total, again
 7 good or bad, that my opinions that have formed
 8 over the course of 25 years should be in here in
 9 case I need to reference it. But, you know, did
 10 I read every word that's here in the last three
 11 months, no.

12 Q. I'm just -- I'm just trying to
 13 clarify. It would be incorrect for a juror or
 14 anyone else to look at this long reliance list
 15 and assume that you have done a comprehensive
 16 review and exam of everything in this list since
 17 becoming involved in this case three months ago?

18 MR. ROSENBLATT: Object to form.
 19 Asked and answered.

20 A. So, right, as I said, my opinions
 21 that are in my report are based on 25 years of
 22 experience, and many of those articles that have
 23 shaped my opinion are listed here in the reliance
 24 list.

25 Q. Okay. What, if any, Ethicon

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1 internal documents did you review in conjunction
 2 with generating your general causation report in
 3 this case?

4 MR. ROSENBLATT: Object to form.
 5 It's on the reliance list.

6 A. Right, so it includes -- it can't
 7 be exclusive or else I can't -- my mind doesn't
 8 think that way, but it includes certainly
 9 e-mails. It includes design specifications of
 10 failure mode analysis, discussions, you know,
 11 animal studies, the IFUs. Those are the types of
 12 internal documents that I reviewed.

13 Q. If there are any internal
 14 documents -- strike that.

15 If there are any Ethicon internal
 16 documents you reviewed in conjunction with
 17 generating your report, they're contained in this
 18 reliance list that's included with Exhibit --

19 MR. ROSENBLATT: I don't know if
 20 you marked it to be honest.

21 Q. -- No. 1 of your deposition. That
 22 (indicating).

23 Is that correct, Doctor?

24 A. I did the best I could to make sure
 25 that what's listed in the reliance list

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1 represents the documents that I reviewed for my
 2 general report. Is that what the question was?
 3 Q. Yeah, pretty much.
 4 Are you aware of any Ethicon
 5 internal documents that you reviewed in
 6 conjunction with generating your report that are
 7 not in your reliance list?
 8 A. Not that I'm aware of.
 9 Q. Are the 30 depositions -- strike
 10 that.
 11 Are the 30 or so depositions that
 12 are listed at the tail end of your reliance list
 13 included in those boxes over there?
 14 A. I'm not sure, and I'll tell you why
 15 I'm not sure. Some material was sent to me by
 16 e-mail or -- not Dropbox but some other. And so
 17 some of -- and there were redundancies. So there
 18 are some things that are there, some things that
 19 I have, and I kind of went between the two when I
 20 reviewed them.
 21 Q. So you don't know?
 22 A. I don't know. Can I just say
 23 something?
 24 Q. Yeah.
 25 A. I got kind of tired of lugging

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1 around those boxes between my house and my
 2 office, that's the truth. You have no idea.
 3 Q. Oh, I do. I do.
 4 A. Oh, my God.
 5 Q. How many times have you been
 6 deposed over the course of your career?
 7 A. I don't keep a list, but it has got
 8 to be about 25 to 30 times, I guess.
 9 Q. Any idea of how many of those were
 10 depositions involving synthetic mesh litigation?
 11 A. No. At least, at least a handful.
 12 At least, you know, five or ten.
 13 Q. Have you ever testified in a trial
 14 of a synthetic mesh case?
 15 A. I don't know for sure. I know I
 16 once was -- it was sort of like a -- maybe you
 17 know what it's called. It was like a video
 18 deposition, but it was going to be used at trial,
 19 right, and it was actually a plaintiff case
 20 involving TVT. I was a plaintiff expert. But I
 21 don't think it actually went to trial, so.
 22 Q. Okay. You've never gone to the
 23 courthouse and taken the witness stand and
 24 testified in front of a judge and jury?
 25 A. Sure I have.

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1 Q. Okay. How many times?
 2 A. Maybe about a dozen.
 3 Q. When was the most recent?
 4 A. Oh, it's got to be -- definitely
 5 within the last year. You know, I could get that
 6 information for you. In fact, I think I -- we
 7 produced something I believe in my report
 8 about -- I think about trials that I've testified
 9 in in the last four years.
 10 Q. Is it in your CV?
 11 A. No. In the CV? No, it wouldn't be
 12 in the CV.
 13 Q. Okay. I saw some stuff in your
 14 report about it.
 15 A. Where?
 16 Q. I've seen some things in your
 17 report.
 18 A. Yeah, I thought so, too.
 19 Q. It's on page 4.
 20 A. Oh. That's it.
 21 Q. "Within the last four years I have
 22 testified as an expert in the cases of Hayes v.
 23 Jordan; Vercher, Bryant, Smith v. Milhorat; Banks
 24 v. Witkowski; Watts v. Davidson; and Taylor-Ricci
 25 v. Coutinho and Staffer," is that right?

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1 A. Yes.
 2 Q. Are any of those cases involving
 3 synthetic mesh?
 4 A. I don't remember. I believe -- I
 5 don't remember. I don't remember.
 6 Q. Well, which one of those cases is
 7 the one you testified at trial in within the past
 8 year?
 9 A. Oh. I'd have to look. I just
 10 don't remember.
 11 Q. It's one of these that's listed,
 12 though?
 13 A. I believe so. I don't remember.
 14 Q. Do you keep anywhere a log of your
 15 experience testifying whether it be in deposition
 16 or in trials?
 17 A. No. I know I had to put together a
 18 list at one point, and I thought I did a couple
 19 years ago with -- when I did some work for Bard.
 20 Not for Bard. I was working with Greenberg
 21 Taurig in Bard litigation for mesh, and I think
 22 I had to put together a list for that, and I
 23 thought that's where this came from. I don't
 24 keep track per se of my depositions. I'm sure I
 25 could find out if you need that information, like

<p style="text-align: right;">Page 138</p> <p>1 when was the last time I testified. I just don't 2 remember.</p> <p>3 Q. Have you ever been retained as an 4 expert witness by Bard?</p> <p>5 A. Not by Bard. By Greenberg Traurig, 6 and they represent Bard.</p> <p>7 Q. Okay. Have you ever been hired as 8 an expert witness aligned with the defense of 9 Bard?</p> <p>10 A. Isn't that what we just said?</p> <p>11 Q. You know what I'm asking you.</p> <p>12 A. I do, but what I'm saying is, and I 13 think it's important to make the distinction, 14 honestly, is that when -- just like in this case, 15 they asked me -- they didn't say, you know, we're 16 hiring you to defend Ethicon or we're hiring you 17 to defend Bard. They're, like, here's the 18 information. We want your honest opinion. 19 Whether you think something, you know, is going 20 on here that we should know about, you know, 21 whether it's good or bad, what is your honest 22 opinion, and that's what I always do whenever I 23 do any kind of legal work.</p> <p>24 MR. CRAWFORD: Objection. 25 Non-responsive, move to strike.</p>	<p style="text-align: right;">Page 140</p> <p>1 attorneys representing Boston Scientific 2 Corporation in cases involving transvaginal mesh?</p> <p>3 A. No.</p> <p>4 Q. Have you ever been hired by 5 attorneys representing American Medical Systems 6 or AMS in cases involving transvaginal mesh?</p> <p>7 A. No.</p> <p>8 Q. Have you been hired by attorneys 9 representing any other transvaginal mesh 10 manufacturer other than Ethicon and Bard?</p> <p>11 A. No.</p> <p>12 Q. When you were hired by the 13 attorneys representing Bard, did you generate a 14 general causation report?</p> <p>15 A. Yes.</p> <p>16 Q. Did you also generate case-specific 17 expert opinions?</p> <p>18 A. Yes.</p> <p>19 Q. On how many different individual 20 cases?</p> <p>21 A. I think it was -- oh, I think it's 22 about 20.</p> <p>23 Q. How long ago was that?</p> <p>24 A. Maybe a year and a half or two 25 years ago.</p>
<p style="text-align: right;">Page 139</p> <p>1 Have you ever been involved in any 2 cases involving Bard?</p> <p>3 A. When you say involving Bard, what 4 do you mean.</p> <p>5 Q. Like women suing Bard.</p> <p>6 A. Well, I guess -- well, so put it 7 this way, I know I've been -- I've been involved 8 in cases where Board products have been used, and 9 I've been retained by attorneys representing 10 physicians, but then, I think it's probably two 11 years ago, I was retained by Greenberg Traurig as 12 part of the MDL, you know, to give my opinion 13 about a number of cases. And, again, similar to 14 this, general report about Bard products and then 15 a number of cases of women who were involved in 16 the MDL against Bard. Does that answer your 17 question?</p> <p>18 Q. Yeah, I'm trying to figure out how 19 I can ask it in a way where you can answer it.</p> <p>20 A. Okay.</p> <p>21 Q. Have you ever been hired by 22 attorneys representing Bard in litigation that 23 involves transvaginal mesh?</p> <p>24 A. Yes.</p> <p>25 Q. Have you ever been hired by</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. Did any of those Bard cases go to 2 trial?</p> <p>3 A. Not that I'm aware of. Not that 4 anyone made me aware of.</p> <p>5 Q. You teach for Boston Scientific 6 Corporation?</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 A. I don't teach for them, but they 9 have asked me to be an instructor at courses on 10 various topics, transvaginal mesh, slings, 11 laparoscopic sacrocolpopexy.</p> <p>12 Q. Have you taught similar courses for 13 Ethicon?</p> <p>14 A. I have.</p> <p>15 Q. When was the last time?</p> <p>16 A. Going back quite a long time ago. 17 It's probably been, oh, gosh, maybe, you know, 18 seven years, I would guess. Seven or eight 19 years.</p> <p>20 Q. Do you know what course it was?</p> <p>21 A. There were a number of courses. 22 You know, there was a number of cadaver labs 23 for -- you know, going back to the early 2000s, 24 you know, TVT, TVT-O, Prolift, and I believe 25 early on maybe even involved TVT Secur. I don't</p>

<p style="text-align: right;">Page 142</p> <p>1 think there were any other products that I taught 2 on, I don't think. Yeah.</p> <p>3 Q. Did I hear you say earlier that 4 whenever you were contacted by Butler Snow who 5 represents Ethicon in this litigation you asked 6 Butler Snow to provide you with literature and 7 research materials for you to review in 8 conjunction with generating your report?</p> <p>9 A. In addition to research I did 10 myself, yes.</p> <p>11 Q. Percentage-wise when we look at 12 your reliance list, what percentage of the 13 materials on that list are things that you came 14 up with yourself as opposed to being provided by 15 Butler Snow?</p> <p>16 MR. ROSENBLATT: Object to form. 17 Asked and answered.</p> <p>18 A. Yeah. I mean -- by the way, excuse 19 me, it's difficult to answer that just because so 20 many of the things that I had in my possession 21 they sent me duplicates of, including abstracts, 22 papers.</p> <p>23 So, you know, maybe, maybe 20 24 percent of the studies, you know, that I hadn't 25 seen before, but then, you know, obviously, I'd</p>	<p style="text-align: right;">Page 144</p> <p>1 MR. CRAWFORD: Do you have any 2 questions, Paul?</p> <p>3 MR. ROSENBLATT: Yeah, I'll have 4 some. And if you want to give me a little bit of 5 time with the Doctor, we'll try to pull the 6 studies that you asked for.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. And there was another one, too, 9 right?</p> <p>10 A. Yeah, the dyspareunia -- the path 11 reports with the resection of the mesh, right?</p> <p>12 Q. Okay.</p> <p>13 A. Chronic pain versus voiding 14 dysfunction. Yeah, that's it.</p> <p>15 Q. Okay. For the time being I'll pass 16 the witness.</p> <p>17 (A break was taken.)</p> <p>18</p> <p>19 EXAMINATION</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. Dr. Rosenblatt, my name is Paul 22 Rosenblatt from Butler Snow representing Ethicon 23 and Johnson & Johnson.</p> <p>24 You were asked some questions today 25 about Dr. Rosenzweig's report. Do you recall</p>
<p style="text-align: right;">Page 143</p> <p>1 never seen any of the internal documents. 2 Obviously, I had seen the IFUs, you know, and I 3 had seen videos that I had from years ago. So 4 it's really difficult to say.</p> <p>5 Q. Some of the videos that appear on 6 your reliance list were provided to you by Butler 7 Snow?</p> <p>8 A. Yes.</p> <p>9 Q. A couple of breaks ago you were 10 going to look up the literature that supports 11 your opinion that polypropylene is inert and not 12 chemically reactive. Have you had an opportunity 13 to do that?</p> <p>14 MR. ROSENBLATT: If we could take a 15 more extended break --</p> <p>16 MR. CRAWFORD: Sure. I'm honestly 17 asking if he had a chance to grab it yet.</p> <p>18 MR. ROSENBLATT: I don't think so. 19 We weren't sure how long you were going to go. 20 If you want to take a lunch break, we can try to 21 do it over lunch.</p> <p>22 MR. CRAWFORD: No, we're on the 23 tail end of this.</p> <p>24 THE WITNESS: We can pull it in a 25 very short period of time.</p>	<p style="text-align: right;">Page 145</p> <p>1 that?</p> <p>2 A. Yes.</p> <p>3 Q. And, in fact, that report was 4 Dr. Rosenzweig's TVT report, right?</p> <p>5 A. Correct.</p> <p>6 Q. And you were asked a significant 7 number of questions about TVT in this deposition?</p> <p>8 A. Yes.</p> <p>9 Q. And stress urinary incontinence 10 procedures?</p> <p>11 A. Yes.</p> <p>12 MR. ROSENBLATT: And, Counsel, I 13 think you'll stipulate that this deposition will 14 also satisfy as the TVT general deposition?</p> <p>15 MR. CRAWFORD: I don't know that 16 I'm qualified to make any sort of stipulation 17 like that.</p> <p>18 MR. ROSENBLATT: Don't sell 19 yourself short like that.</p> <p>20 Would it be fair to say, Doctor, 21 that in addition to reviewing -- strike that.</p> <p>22 Would it be fair to say, Doctor, 23 that you considered not only Dr. Rosenzweig's 24 report but also the reports from other 25 plaintiffs' experts regarding Ethicon's prolapse</p>

<p style="text-align: right;">Page 146</p> <p>1 and SUI products.</p> <p>2 A. Yes.</p> <p>3 Q. And, in fact, you mentioned that</p> <p>4 you asked for the good and bad. Did you in fact</p> <p>5 review a significant number of the materials</p> <p>6 cited in plaintiffs' experts reports?</p> <p>7 MR. CRAWFORD: Objection to form.</p> <p>8 A. Yes.</p> <p>9 Q. And that would include internal</p> <p>10 documents and medical literature that plaintiffs'</p> <p>11 experts referred to?</p> <p>12 A. Yes.</p> <p>13 Q. And did reviewing any of those</p> <p>14 materials change your opinions about the safety</p> <p>15 and efficacy of Ethicon's prolapse and</p> <p>16 incontinence products?</p> <p>17 A. I took it into consideration, but</p> <p>18 it didn't change my opinions.</p> <p>19 Q. And in addition to our law firm</p> <p>20 providing you with some of the materials</p> <p>21 referenced in your reliance list, would it be</p> <p>22 fair to say that a significant number of those</p> <p>23 materials you had already seen previously?</p> <p>24 A. Yes.</p> <p>25 Q. And, in fact, that's part of your</p>	<p style="text-align: right;">Page 148</p> <p>1 courses, and I teach quite a bit of CME courses</p> <p>2 here and regionally and nationally, and I also</p> <p>3 present quite a bit at national and international</p> <p>4 meetings. But specifically with Ethicon products</p> <p>5 I started doing some teaching probably back in</p> <p>6 the year, I would imagine, 2000, and I've done a</p> <p>7 number of -- many cadaver courses educating</p> <p>8 surgeons on proper use of Ethicon products which</p> <p>9 started out, you know, with TVT but then TVT-O</p> <p>10 and Prolift as well.</p> <p>11 Q. Did you ever feel like you were</p> <p>12 being influenced by Ethicon to promote their</p> <p>13 products?</p> <p>14 A. Absolutely not. It has always been</p> <p>15 very important to me to offer my patients the</p> <p>16 best treatment. So, you know, I never wanted to</p> <p>17 be seen that I was working for one company. I</p> <p>18 use the products on my patients that I think are</p> <p>19 the best. I've used products from various</p> <p>20 companies, and as well as just, you know, not</p> <p>21 always products, right? I mean, you know,</p> <p>22 techniques and, you know, custom-made pieces of</p> <p>23 mesh. And if I believe in a product like I</p> <p>24 believe in, you know, TVT or Prolift, then I</p> <p>25 would agree to, you know, to instruct surgeons on</p>
<p style="text-align: right;">Page 147</p> <p>1 job as a physician, is to continuously review the</p> <p>2 medical literature?</p> <p>3 A. It's my job as a physician, and</p> <p>4 it's also my job as an educator. You know, I</p> <p>5 have residents and medical students and fellows</p> <p>6 that I teach. I do a lot of teaching around the</p> <p>7 country and around the world, and I feel it's</p> <p>8 important to stay up on the literature.</p> <p>9 Q. And where do you -- just so we have</p> <p>10 an understanding -- I know we could run through</p> <p>11 your CV, but Doctor, where do you teach?</p> <p>12 A. Primarily at Mount Auburn Hospital</p> <p>13 which is a community teaching hospital of Harvard</p> <p>14 Medical School.</p> <p>15 Q. And in addition to teaching</p> <p>16 residents and fellows at Harvard, are you also</p> <p>17 teaching continuing medical education across the</p> <p>18 country?</p> <p>19 MR. CRAWFORD: Objection to form.</p> <p>20 A. Yes.</p> <p>21 Q. And are you -- strike that.</p> <p>22 If you could just describe some of</p> <p>23 your experience teaching professional education</p> <p>24 for the Ethicon products?</p> <p>25 A. So in addition to, you know, CME</p>	<p style="text-align: right;">Page 149</p> <p>1 the correct use. But there were times I've been</p> <p>2 asked to, you know, teach for products that I</p> <p>3 wasn't -- that I didn't believe in, that I didn't</p> <p>4 use, and I wouldn't teach those products.</p> <p>5 Q. And Doctor, were you paid for your</p> <p>6 time to teach professional education?</p> <p>7 A. Yes.</p> <p>8 Q. And how did -- the amount that you</p> <p>9 were paid for your time teaching or strike that.</p> <p>10 Doctor, what was the opportunity</p> <p>11 cost of you teaching professional education as</p> <p>12 far as --</p> <p>13 A. So let's clarify that for a moment.</p> <p>14 So when I teach a CME course, most often it</p> <p>15 doesn't involve any payment to me. That's</p> <p>16 something that I do 'cause I really enjoy</p> <p>17 teaching, and I think it's a really important</p> <p>18 thing for some surgeons who are dedicated to do</p> <p>19 that type of work. But when it involved a</p> <p>20 specific company like Ethicon, they were often,</p> <p>21 you know, taking time away from my practice, and</p> <p>22 so, you know, I think I was compensated fairly</p> <p>23 for that because that's the opportunity cost.</p> <p>24 I'm not seeing patients in the office, and I'm</p> <p>25 not doing surgery on those days. But there's</p>

<p style="text-align: right;">Page 150</p> <p>1 also teaching in the evenings and teaching on 2 weekends that took me away from my family, but I 3 really enjoyed the teaching, and I think I was 4 compensated, you know, appropriately for that. 5 Q. So did you teach professional 6 education because you wanted the money? 7 A. It was not -- it's never been about 8 the money. It's been about teaching proper use 9 of devices. And I've always seen it as not the 10 responsibility of the companies themselves to do 11 the teaching but of the surgeons who are thought 12 leaders in our industry to properly instruct 13 other surgeons on how to use products 14 appropriately. 15 Q. And I think that's what you 16 referred to earlier as, what, peer-to-peer 17 teaching? 18 A. Correct. 19 Q. And, Doctor, in addition to the 20 material -- well, the materials referenced in 21 your report, would it be fair to say that not 22 only have you reviewed a significant number of 23 those materials prior to becoming involved in the 24 litigation but that you in addition to reviewing 25 those materials performed your own PubMed</p>	<p style="text-align: right;">Page 152</p> <p>1 prospective studies or even retrospective cohort 2 studies that provide some use and are considered 3 generally Level II evidence, but they're not as 4 high as the Level I evidence. So we tend to in 5 general in all of medicine, not just in surgery 6 but also in medicine looking at, you know, drugs, 7 et cetera, that Level I evidence is the most 8 important. 9 Q. And when you look at that Level I 10 evidence, for example, the randomized controlled 11 trials for prolapse meshes involving 12 polypropylene and specifically Ethicon's 13 Gynemesh® PS and Prolift, what is the statistical 14 significance, if any, when those RCTs compare 15 native tissue repairs to mesh repairs for 16 prolapse? 17 A. Well, there are a couple of ways of 18 looking at it. And when you look at objective 19 success, in other words, based on pelvic 20 examination, across the board the success rate is 21 significantly higher for transvaginal mesh. It's 22 become widely accepted in our field that it's 23 important to look at subjective outcome as well 24 and coming up with like a composite score. And 25 there's good Level I evidence as well that</p>
<p style="text-align: right;">Page 151</p> <p>1 searches to satisfy yourself of the medical 2 literature? 3 A. Yes. 4 Q. And when you were asked questions 5 about the levels of evidence, if you could just 6 explain why Level I and Level II evidence is 7 significant to you? 8 A. Yeah. So there are many -- there 9 are many reports out in the literature, and they 10 vary in terms of their quality, and it's 11 generally recognized that the highest quality 12 studies are randomized prospective studies or 13 RCTs, randomized controlled trials, and 14 obviously, there are other Level I evidence or 15 ways to kind of synthesize all the data that's 16 put together which is referred to as a 17 meta-analysis. And a meta-analysis is a 18 statistical form where you can pool data from 19 high level studies to try to make sense on a 20 grander scale of the significance. And then also 21 systematic reviews where you have a, you know, a 22 question that you want answered and you look at 23 all the high quality evidence, and it's a matter 24 of, you know, throwing out studies that aren't as 25 useful. You know, there are still studies like</p>	<p style="text-align: right;">Page 153</p> <p>1 subjective outcome is either improved or not 2 significantly different from native tissue 3 repair, but in total, you're going to prevent 4 recurrences from happening with transvaginal mesh 5 compared to native tissue repairs. 6 Q. And when you look at the randomized 7 controlled trials for transvaginal mesh to treat 8 prolapse versus native tissue repairs, is there 9 any statistical significance regarding de novo 10 dyspareunia? 11 A. You know, that's something we talk 12 about as, you know, mesh and dyspareunia, but 13 when you look at the randomized controlled 14 trials, there is no statistically significant 15 difference in the highest level studies. In 16 fact, there are studies that show less de novo 17 dyspareunia with transvaginal mesh compared to 18 native tissue repair. 19 Q. And I believe in your expert report 20 you referred to specifically the Withagen study 21 to support that? 22 A. Correct. 23 Q. Okay. And would the same be true, 24 Doctor, for pelvic pain and just general quality 25 of life?</p>

<p style="text-align: right;">Page 154</p> <p>1 A. Those are -- those as well. 2 There's no statistically significant difference 3 between native tissue repairs and transvaginal 4 mesh when you look at those. 5 Q. And it's important to look at those 6 subjective factors in the context of a randomized 7 controlled trial to make sure you're not 8 comparing apples and oranges but that you're 9 comparing apples to apples; is that fair? 10 A. That's correct. 11 Q. Doctor, two of your invoices were 12 marked as I believe Exhibits 4 and 5. Would it 13 be fair to say that you charged for your time in 14 performing the research and rendering your 15 opinions in this litigation? 16 A. As best I can, yes. 17 Q. And, in fact, there was a charge of 18 your deposition rate that you submitted on your 19 invoice because -- not because of counsel's fault 20 but your deposition was originally scheduled 21 several weeks ago and was cancelled at the last 22 minute; is that fair? 23 A. I remember distinctly. The 24 deposition was scheduled for a Monday, and I 25 found out that the deposition was cancelled on a</p>	<p style="text-align: right;">Page 156</p> <p>1 Q. And you mentioned Female Pelvic 2 Medicine Reconstructive Surgery, that would be 3 abbreviated FPMRS? 4 A. Right. 5 Q. Is that a subspecialty in your 6 field? 7 A. Correct. 8 Q. And that would be a board 9 certification? 10 A. Correct, it became a board 11 certification I think it was 2013. 12 Q. And so if Dr. Rosenzweig has not 13 sat for the FPMRS board, then he would not be a 14 board-certified urogynecologist? 15 A. That's right. 16 Q. You are, though, right? 17 A. I am. 18 Q. And are you in fact an examiner for 19 the FPMRS exam? 20 A. Yeah, I'm actually a board examiner 21 for the general boards, but I just transitioned 22 to being a board examiner for the subspecialty of 23 FPMRS. 24 Q. So it would be fair to say, then, 25 Doctor, that you would have a good understanding</p>
<p style="text-align: right;">Page 155</p> <p>1 Saturday. And Monday is -- Mondays and Wednesday 2 are my primary surgical days, and I have block 3 time, and that day would have been filled with, 4 you know, three to six cases, and a week before 5 the block time, the block gets released, and 6 there's no way to -- so that was a wasted day, a 7 completely wasted day. 8 Q. And, Doctor, we talked a little bit 9 about some of your teaching experience contained 10 on your CV, but would it be fair to say that 11 you've published a significant number of studies 12 in the medical literature on incontinence and 13 prolapse? 14 A. Right, primarily my field of 15 interest is prolapse, urinary incontinence and 16 fecal incontinence. 17 Q. And are you involved in any 18 editorial activities such as reviewing for 19 medical journals? 20 A. Yes, I'm a peer reviewer for a 21 number of journals, and I've been on the 22 editorial board of the Gold journal which is the 23 Journal of Female Pelvic Medicine Reconstructive 24 Surgery and also the JMIG which is more of the 25 minimally invasive gynecologic surgery.</p>	<p style="text-align: right;">Page 157</p> <p>1 of what fellows and surgeons are expected to know 2 in your field about procedures and risks 3 associated with those procedures including pelvic 4 mesh, correct? 5 MR. CRAWFORD: Objection to form. 6 A. No, that's correct. That's -- you 7 know, what we do as board examiners is -- I'm 8 very familiar with the standard of care, and we 9 are making sure that people who are quali- -- you 10 know, that the only people who become board 11 certified are qualified to do so and are 12 performing within the standard of care. 13 Q. And, for example, would you test 14 fellows and surgeons on their knowledge of 15 potential complications of mesh-based repairs for 16 incontinence and prolapse? 17 A. Yes. 18 Q. And how to manage those 19 complications that may occur? 20 A. Correct. 21 Q. And the same would be true for 22 native tissue repairs for stress urinary 23 incontinence and pelvic organ prolapse? 24 A. Correct. 25 Q. Doctor, you were asked some</p>

<p style="text-align: right;">Page 158</p> <p>1 questions about whether or not mesh exposure was 2 a serious complication. Do you recall that line 3 of questioning? 4 A. Yes. 5 Q. In your experience, are mesh 6 exposures typically considered serious 7 complications? 8 A. So the vast majority of them are 9 not from a clinical standpoint considered serious 10 complications. Could there be a mesh erosion? 11 Let's take away exposures. Could there be a mesh 12 exposure that's serious? Yeah, it could happen. 13 You know, I've seen a couple examples in 15 years 14 of patients who have developed hematomas who have 15 opened their incision and have large mesh 16 exposures but the vast majority, I'm talking 17 about over 95 percent of them, are usually minor 18 mesh exposures that can either be taken care of 19 in the office or can be taken care of in an 20 operating room under local anesthesia with 21 conscious sedation. So how we look at them as 22 clinicians versus how the FDA classifies them 23 because it's a return trip to the OR, there's a 24 disparity there. 25 Q. And if there is a complication</p>	<p style="text-align: right;">Page 160</p> <p>1 were some mesh exposures with the mesh group, did 2 that translate into any statistical significant 3 difference with respect to dyspareunia or pelvic 4 pain? 5 MR. CRAWFORD: Objection to form. 6 A. No, it did not. 7 Q. And if you look on the next page, 8 34, you cite to the Heinonen 2016 study. 9 A. Yes. 10 Q. And although you describe here that 11 the authors reported a 23 percent mesh exposure 12 rate, you note that the exposures were 13 asymptomatic in 24 of 32 or 66.7 percent of 14 patients. Do you see that? 15 A. That's correct. 16 Q. So, if you could, just describe 17 whether or not an asymptomatic mesh exposure 18 would be of any clinical concern? 19 A. So it depends on the situation but, 20 you know, many women do have small mesh exposures 21 and are not aware of it, and it doesn't pose any 22 danger to the patient, and there's no reason to 23 treatment an asymptomatic mesh exposure. And 24 when I say asymptomatic, I'm talking about for 25 the patient, and if the patient is sexually</p>
<p style="text-align: right;">Page 159</p> <p>1 associated with a native tissue repair, does that 2 get reported to a MAUDE database? 3 A. No, because it doesn't involve -- 4 as far as I know, it doesn't involve a device, so 5 no one would report it to a MAUDE database. 6 Q. And so when you were seeing you 7 didn't necessarily agree with the FDA's 2011 8 public health notice description as complications 9 are not rare, was that in part because they did 10 not consider the complications that occur with 11 native tissue repairs? 12 A. Correct. 13 Q. And was that also in part because 14 when you performed the mathematical calculation 15 as you described, 0.6 percent would in fact be 16 rare? 17 A. In my book, that's very rare. 18 Q. Doctor, if we look at your expert 19 report, starting on page 33. 20 A. Yes. 21 Q. In the middle of the page, you cite 22 to the Damoiseaux 2015 RCT. Do you see that? 23 A. Yes. 24 Q. A little further down they describe 25 a mesh exposure rate, but then, even though there</p>	<p style="text-align: right;">Page 161</p> <p>1 active, to her partner. So, obviously, if the 2 patient didn't have symptoms but her partner had 3 symptoms, then that would be symptomatic, but the 4 majority of these mesh exposures are asymptomatic 5 to the patient and her partner. 6 Q. And, Doctor, I don't want to rehash 7 everything that's already in the report, but 8 would it be fair to say if you continue flipping 9 the pages that you describe a significant number 10 of studies and the reported outcomes to include 11 success rates and complications of those studies 12 involving Prolift and Gynemesh® PS? 13 A. Yes. 14 Q. And I do want to look at one in 15 particular on page 37. Towards the bottom you 16 cite to De Landsheere and Cosson in 2011 which 17 was a three-year follow-up study of 524 patients, 18 and then on the next page, could you just 19 describe some of the complications that were 20 noted in this large patient study? 21 MR. CRAWFORD: Objection to form. 22 A. So in that study, which I believe 23 was a cohort study -- it was not one of the 24 randomized controlled trials, but it was a very 25 large study because it had, you know, so many</p>

<p style="text-align: right;">Page 162</p> <p>1 patients in it -- the total mesh-related 2 complications was 3.6 percent with a mesh 3 exposure rate of 2.7 percent which is relatively 4 low. And the other important part about this 5 study was that most of the mesh exposures 6 occurred in the first year of the study, so we're 7 not seeing mesh exposures that are continually 8 coming out. It's usually during the healing 9 process when you see a mesh exposure. 10 Q. Is that supported by additional 11 studies that you've seen in the medical 12 literature? 13 A. Yes. 14 Q. And would that also be supported by 15 your clinical experience? 16 A. Yes. 17 Q. Would that also be supported by 18 your discussions with colleagues? 19 A. Yes. 20 Q. And what did the De Landsheere 21 study find with respect to severe symptomatic 22 mesh retractions? 23 A. That it was found in an extremely 24 low number of patients of less than half a 25 percent.</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Mm-hmm, yes. 2 Q. Do you know if there's literature 3 to suggest that urethral sphincters can erode? 4 A. Urethral sphincters, anal 5 sphincters, anything in that area can erode. 6 Q. And, Doctor, you were asked a 7 number of questions regarding Dr. Rosenzweig's 8 TVT report and whether or not you agreed or 9 disagreed with those opinions. Do you recall 10 that? 11 MR. CRAWFORD: Objection to form. 12 A. Yes. 13 Q. And a lot of those questions dealt 14 with properties of the mesh and potential 15 complications of mesh; is that fair? 16 A. Yes. 17 Q. If you could, just -- I know you 18 have a lot of that in your expert report, but if 19 you could just briefly describe your experience 20 with mesh design and mesh properties? 21 MR. CRAWFORD: Objection to form. 22 A. Well, I've actually -- I personally 23 have been -- besides reading the literature, 24 which I'm very familiar with, but I've also had 25 the opportunity to work with a number of</p>
<p style="text-align: right;">Page 163</p> <p>1 Q. And would that be consistent with 2 what you would expect from Prolift? 3 A. Yes. 4 Q. Doctor, you were describing some 5 factors that could contribute to mesh exposures 6 earlier. Do you recall that testimony? 7 A. Yes. 8 Q. And I believe you mentioned surgeon 9 technique and other patient factors. So would it 10 be fair to say that there are factors unrelated 11 to the mesh itself that contribute to mesh 12 exposures? 13 A. Yes, that's widely accepted. 14 Q. And I believe you also testified 15 that exposure or erosion is not necessarily 16 unique to mesh because you can also have a suture 17 erosion or exposure; is that correct? 18 A. Correct. 19 Q. Okay. Would that be true for any 20 foreign body implant? 21 A. Absolutely. 22 Q. Do you implant urethral sphincters? 23 A. I do not. 24 Q. Do you know if urologists in your 25 field do?</p>	<p style="text-align: right;">Page 165</p> <p>1 companies on mesh designed. And so I've worked 2 with engineers on some of my own products and 3 some with companies and some completely 4 independent. 5 So, you know, I've approached -- 6 for instance, there's a company in Rhode Island 7 called Biomedical Structures that I, right 8 outside of Providence, that I worked with them on 9 some of my own mesh designs. So I'm very 10 familiar with design of polypropylene mesh. 11 I've also worked, again, 12 personally, not with a company, with a mesh 13 manufacturer in Ireland called Proxy Medical that 14 actually does make some mesh for some companies 15 in the United States, including Boston 16 Scientific, on devices that I've designed. So 17 I've worked with engineers, design engineers, on 18 mesh design. 19 MR. CRAWFORD: Objection. 20 Non-responsive. 21 Q. And would it be fair to say that 22 you also have -- strike that. 23 Doctor, could you describe your 24 experience, if any, with respect to taking a new 25 product through the regulatory cycle and drafting</p>

<p style="text-align: right;">Page 166</p> <p>1 IFUs?</p> <p>2 MR. CRAWFORD: Objection to form.</p> <p>3 A. Yeah, so I've been very fortunate</p> <p>4 that I've taken -- there was one device that I</p> <p>5 worked on -- that I've been working on since 2004</p> <p>6 which is a mesh device, very similar to the</p> <p>7 Prolene® mesh. It was actually with American</p> <p>8 Medical Systems. It was actually very similar to</p> <p>9 the SPARC mesh that they use, but it was</p> <p>10 different. It had additional fibers added to it.</p> <p>11 And that's something I worked with them from 2007</p> <p>12 'til this year on designing the mesh, working on</p> <p>13 the device of the IFUs and other materials,</p> <p>14 including, you know, animations and online</p> <p>15 training, et cetera.</p> <p>16 So I've taken that product from the</p> <p>17 beginning through IDE studies, investigational</p> <p>18 device exemption studies, and the PMA process,</p> <p>19 premarket approval I think it stands for. So</p> <p>20 I've been very involved in that type of design.</p> <p>21 Plus, I wrote much of the instructions for use,</p> <p>22 the IFUs, for that device.</p> <p>23 MR. CRAWFORD: Objection.</p> <p>24 Non-responsive.</p> <p>25 Q. And, Doctor, as part of your</p>	<p style="text-align: right;">Page 168</p> <p>1 is basically encompassing what is in an IFU.</p> <p>2 Q. And if you had any concerns about</p> <p>3 Ethicon's IFUs for the TVT products or the</p> <p>4 Gynemesh® PS or the Prolift devices as being</p> <p>5 inadequate, would you have voiced your concerns?</p> <p>6 A. Yes.</p> <p>7 Q. And in your opinion, are those</p> <p>8 IFUs, all the versions that you've reviewed,</p> <p>9 adequate?</p> <p>10 MR. CRAWFORD: Objection to form.</p> <p>11 A. Yes, they are.</p> <p>12 Q. And you were asked some questions</p> <p>13 about your legal work, Doctor. Would it be fair</p> <p>14 to say that you have been an expert for both</p> <p>15 sides, both plaintiffs and defendants?</p> <p>16 A. Yes, I have. I would say more so</p> <p>17 for defense, but I have done plaintiff work as</p> <p>18 well.</p> <p>19 Q. Doctor, you were asked about</p> <p>20 shrinkage and whether or not -- I believe it was</p> <p>21 couched just in broad terms about mesh shrinkage.</p> <p>22 Do you recall those questions?</p> <p>23 A. Yes.</p> <p>24 Q. I believe one of the documents that</p> <p>25 you cited to was the Dietz paper.</p>
<p style="text-align: right;">Page 167</p> <p>1 experience teaching professional education, would</p> <p>2 you teach on the IFUs?</p> <p>3 A. Right. So when we teach, what</p> <p>4 we're doing is sort of summarizing the IFUs,</p> <p>5 because, you know, the IFUs come with the device,</p> <p>6 right? So when you open up a package in the</p> <p>7 operating room, you're really not going to sit</p> <p>8 there while the patient's under anesthesia and</p> <p>9 read the instructions like you're programming a</p> <p>10 VCR. I don't know if people know what a VCR is</p> <p>11 anymore.</p> <p>12 Q. Good lord.</p> <p>13 A. Yeah, I shouldn't have said that.</p> <p>14 I meant a Beta max. Yeah, I got to rethink that.</p> <p>15 Anyway, so I think the way most</p> <p>16 surgeons learn how to use a device is by, or</p> <p>17 should learn how to use a device, is by going to</p> <p>18 professional education conferences and learning</p> <p>19 from PowerPoint presentations, animations,</p> <p>20 cadaver dissections, procedural videos. That's</p> <p>21 how people really learn.</p> <p>22 Q. By medical literature?</p> <p>23 MR. CRAWFORD: Objection.</p> <p>24 Non-responsive.</p> <p>25 A. And medical literature. And that</p>	<p style="text-align: right;">Page 169</p> <p>1 A. Yes.</p> <p>2 Q. And what does the Dietz paper</p> <p>3 regarding TVT describe about whether or not TVT</p> <p>4 contracts or shrinks?</p> <p>5 A. So this is one of the studies that</p> <p>6 I relied on, and Dr. Dietz is very well for his</p> <p>7 work on transvaginal ultrasound, and this study</p> <p>8 shows that the TVT does not seem to contract or</p> <p>9 shorten over a period of over a year and a half.</p> <p>10 MR. CRAWFORD: Objection.</p> <p>11 Non-responsive.</p> <p>12 Q. And in another study by Lo, which</p> <p>13 was an ultrasound study, what did Lo and</p> <p>14 colleagues find about whether or not ultrasound</p> <p>15 assessment found any shrinkage or contraction</p> <p>16 with TVT?</p> <p>17 A. They also -- and, again, both of</p> <p>18 these researchers are very well-known. Lo is in</p> <p>19 Taiwan, and showed that TVT does not show any</p> <p>20 shrinkage. And if -- and there's actual clinical</p> <p>21 data to support that, in that if shrinkage did</p> <p>22 occur you'd expect to see patients who were</p> <p>23 initially voiding. If shrinkage occurred, they'd</p> <p>24 go into retention, and we just don't see that</p> <p>25 happening.</p>

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<p>1 MR. CRAWFORD: Objection.</p> <p>2 Non-responsive.</p> <p>3 Q. And do you recall in the 17-year</p> <p>4 Nelson study whether or not they noticed any</p> <p>5 shrinkage of TVT?</p> <p>6 A. They did not notice any shrinkage</p> <p>7 of TVT.</p> <p>8 Q. And would that be consistent with</p> <p>9 your medical practice?</p> <p>10 A. Yes.</p> <p>11 Q. Would that be consistent with your</p> <p>12 discussions with colleagues?</p> <p>13 A. Yes.</p> <p>14 Q. And would that be consistent with</p> <p>15 your general review of the medical literature?</p> <p>16 A. Correct.</p> <p>17 Q. And additionally, another Dietz</p> <p>18 paper that I believe you referred to looked at</p> <p>19 prolapse meshes. I believe in particular the AMS</p> <p>20 Perigee. Do you recall that paper?</p> <p>21 A. Yes.</p> <p>22 Q. Is the Perigee similar to the</p> <p>23 Prolift?</p> <p>24 MR. CRAWFORD: Objection to form.</p> <p>25 A. It's similar in that it is a Type 1</p>	<p>1 still perform open Burchs on a regular basis?</p> <p>2 A. No, I use to, but I haven't done an</p> <p>3 open Burch in probably 20 years.</p> <p>4 Q. And why is that?</p> <p>5 A. Oh, just because we can do the</p> <p>6 exact same procedure in a minimally invasive</p> <p>7 fashion.</p> <p>8 Q. So would it be fair to say that the</p> <p>9 Burch is a -- the open Burch is a more invasive</p> <p>10 procedure than, for example, a midurethral sling?</p> <p>11 A. Significantly more invasive.</p> <p>12 Q. And what are some of the -- strike</p> <p>13 that.</p> <p>14 Now, with regard to the Burch, are</p> <p>15 you familiar with an article by Demirci</p> <p>16 describing the long-term results of the Burch?</p> <p>17 A. Yes.</p> <p>18 Q. And what did this paper by Demirci</p> <p>19 find about the rates of dyspareunia and growing</p> <p>20 pain as late complications of the Burch?</p> <p>21 A. Yeah, so these are potential</p> <p>22 complications in a Burch procedure, and you know,</p> <p>23 dyspareunia occurred in 6 patients out of the</p> <p>24 220, groin or suprapubic pain in 15, which is</p> <p>25 probably about, you know, 7 percent or so, but</p>
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<p>1 macroporous monofilament polypropylene mesh.</p> <p>2 Q. And what was Dietz's conclusion in</p> <p>3 this paper from 2011 about whether or not Perigee</p> <p>4 or transvaginal mesh for prolapse contracted?</p> <p>5 A. Yeah, there was no evidence on</p> <p>6 ultrasound examination of any mesh contraction in</p> <p>7 this study.</p> <p>8 Q. And, Doctor, you were asked some</p> <p>9 questions about biocompatibility and inertness.</p> <p>10 I want to show you a paper that I believe you</p> <p>11 reviewed by Binnebösel. If you could, just</p> <p>12 describe what they noted about mesh integration.</p> <p>13 A. So they stated that these materials</p> <p>14 are physically and chemically inert, stable and</p> <p>15 non-toxic.</p> <p>16 Q. And they're referring to</p> <p>17 polypropylene meshes?</p> <p>18 A. Yes, they are.</p> <p>19 Q. Doctor, you were asked some</p> <p>20 questions about the Burch procedure. When you</p> <p>21 were describing your experience with the Burch,</p> <p>22 were you describing the open Burch or the</p> <p>23 laparoscopic Burch?</p> <p>24 A. Both.</p> <p>25 Q. And do you primarily -- do you</p>	<p>1 there were also other complications including</p> <p>2 enteroceles in over 10 percent of patients and</p> <p>3 rectoceles, and it's felt that the change in the</p> <p>4 axis of the vagina predisposes to posterior,</p> <p>5 which would be rectocele and enteroceles,</p> <p>6 prolapse.</p> <p>7 Q. And would that be a complication</p> <p>8 that would occur more frequently after a Burch</p> <p>9 than after a midurethral sling?</p> <p>10 MR. CRAWFORD: Objection to form.</p> <p>11 A. Yes.</p> <p>12 Q. And it would be fair to say,</p> <p>13 Doctor, that complications such as dyspareunia</p> <p>14 and pain, whether it's short term or chronic, are</p> <p>15 well-known complications of any vaginal</p> <p>16 procedure?</p> <p>17 A. That's correct.</p> <p>18 Q. You were asked some questions about</p> <p>19 degradation, and I believe you referred</p> <p>20 specifically to the Clavé paper.</p> <p>21 A. Yes.</p> <p>22 Q. What did the authors conclude about</p> <p>23 their hypotheses concerning degradation,</p> <p>24 specifically oxidation degradation?</p> <p>25 A. They brought up these as</p>

<p style="text-align: right;">Page 174</p> <p>1 hypotheses, but they stated that none of their 2 hypotheses, and in particular direct oxidation, 3 could be confirmed by the study. 4 Q. So, Doctor, when you said you were 5 not familiar with the literature that described 6 in vivo degradation, would it be fair to say that 7 scientists have tried to study that issue but 8 have not been able to confirm in vivo 9 degradation? 10 MR. CRAWFORD: Objection to form. 11 A. That's correct. 12 Q. And you were asked some 13 hypotheticals, Doctor. Hypothetically if 14 degradation did occur, what in your opinion, 15 based on your clinical experience and your review 16 of the medical literature, would be the clinical 17 significance of degradation if it hypothetically 18 did occur? 19 A. So when it came to like slings, you 20 would expect to see failures, and we're not 21 seeing that. And when it comes to prolapse, then 22 you'd expect over time to see degradation would 23 lead to disappearance of the mesh and failures, 24 and that's just not what we're seeing clinically. 25 Q. And, Doctor, AUGS and SUFU released</p>	<p style="text-align: right;">Page 176</p> <p>1 study by de Tayrac which followed the Clavé 2 study, and you noted earlier this biofilm when 3 you wash it off the mesh wasn't degraded. Could 4 you just describe what the authors found in this 5 study -- 6 MR. CRAWFORD: Objection. 7 Q. -- in 2011? 8 MR. CRAWFORD: Objection to form. 9 A. So what these authors showed is 10 that when you properly washed the material with, 11 in this case, DMSO which is a solvent -- it's 12 actually a byproduct of the wood industry -- and 13 you also used ultrasonic shock, that after the 14 biofilm was removed there is absolutely no 15 polymer degradation, and you know, according to 16 this, scanning electron microscopy image, to my 17 eyes and anyone who would read this, it looks 18 like it's pristine material. 19 MR. CRAWFORD: Objection. 20 Non-responsive. 21 Q. And, Doctor, I believe one of the 22 other studies you were relying on was a recent 23 study from the International Urogynecology 24 Journal by Ong. Do you recall that? 25 A. Yes.</p>
<p style="text-align: right;">Page 175</p> <p>1 a Frequently Asked Questions by Providers 2 regarding midurethral slings for stress urinary 3 incontinence. Have you seen this document 4 before? 5 A. Yeah, I use that with my patients, 6 too. 7 Q. And one of the questions that they 8 ask is does the midurethral sling made of 9 polypropylene degrade over time. Could you just 10 summarize what their response was in this 11 document? 12 MR. CRAWFORD: Objection to form. 13 A. So AUGS and SUFU are the leading 14 organizations for surgeons and patients in 15 urogynecology and female reconstructive surgery, 16 and it's stated here that polypropylene is a 17 stable and well-accepted biomaterial with, as we 18 mentioned, a history of over five decades in 19 use -- of use in mesh implants. And though 20 people have raised the issue of possible 21 degradation, including what we talked about like 22 cracked surfaces, that there's no evidence that 23 that is actually happening. 24 Q. And Doctor, one of the other 25 studies that I believe you relied on was a 2011</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. What did this study conclude about 2 explanted Prolene® meshes and whether or not they 3 underwent any clinically significant degradation? 4 A. Well, they concluded something very 5 similar in that these explanted Prolene® meshes 6 did not undergo any meaningful or harmful 7 degradation in vivo but that the, you know, 8 quote/unquote, cracked layer was actually 9 composed of protein coatings arising from a 10 well-established phenomenon occurring immediately 11 upon implantation which is what we referred to 12 earlier as a biofilm. 13 Q. And, Doctor, you were asked some 14 questions about the MSDS. I represent to you 15 this is the Sunoco MSDS for Ethicon's Prolene®. 16 A. Yes. 17 Q. Would it be fair to say that MSDS, 18 material safety data sheets, are under the 19 purview of OSHA and not the FDA? 20 MR. CRAWFORD: Objection to form. 21 A. That is correct. 22 Q. And so in your opinion would this 23 document have anything to do with the safety of 24 an implantable medical device outside of the 25 context of employees working with various</p>

<p style="text-align: right;">Page 178</p> <p>1 chemicals?</p> <p>2 MR. CRAWFORD: Objection to form.</p> <p>3 A. Right, so the MSDS, as you</p> <p>4 mentioned, is under the purview of OSHA to</p> <p>5 protect workers who are handling materials, but</p> <p>6 we're talking about raw materials. We're not</p> <p>7 talking about devices that are then -- you know,</p> <p>8 this refers to, for instance, like the</p> <p>9 polypropylene pellets and when they're heated up</p> <p>10 and extruded, but that has nothing to do with</p> <p>11 when it's implanted into a human.</p> <p>12 Q. And one of the references I believe</p> <p>13 Dr. Rosenzweig was citing to under</p> <p>14 incompatibility was strong oxidizers such as</p> <p>15 chlorine, peroxides, et cetera, and you were</p> <p>16 asked questions about whether or not mesh would</p> <p>17 undergo oxidative degradation due to peroxides in</p> <p>18 the vagina. Do you recall those questions?</p> <p>19 MR. CRAWFORD: Objection to form.</p> <p>20 A. Yes.</p> <p>21 Q. In your opinion, is that a</p> <p>22 realistic possibility?</p> <p>23 MR. CRAWFORD: Form.</p> <p>24 A. No, there's no evidence of that.</p> <p>25 In addition, you know, again, this is the MSDS</p>	<p style="text-align: right;">Page 180</p> <p>1 show you a paper I believe you relied on by</p> <p>2 Firoozi and Goldman at the Cleveland Clinic.</p> <p>3 A. Yes.</p> <p>4 Q. And this study involves a total of</p> <p>5 23 patients involving removal of mesh, prolapse</p> <p>6 mesh, including Ethicon's Prolift. Do you recall</p> <p>7 that?</p> <p>8 A. I do.</p> <p>9 Q. And, if you could, just describe</p> <p>10 whether or not their removal procedure was</p> <p>11 successful without removing the arms of the mesh?</p> <p>12 MR. CRAWFORD: Objection to form.</p> <p>13 Q. In terms of curing the patient's</p> <p>14 pain?</p> <p>15 A. Well, I think one of the most</p> <p>16 important parts of this study was that they were</p> <p>17 able to show that patients who had pain where</p> <p>18 they determined they wanted to remove the mesh</p> <p>19 that they could remove the mesh safely.</p> <p>20 MR. CRAWFORD: Objection.</p> <p>21 Non-responsive.</p> <p>22 Q. And, Doctor, is that consistent</p> <p>23 with your clinical experience?</p> <p>24 A. It is.</p> <p>25 Q. And if there's an instance where</p>
<p style="text-align: right;">Page 179</p> <p>1 for polypropylene, but then there are additives</p> <p>2 in Prolene® mesh which are antioxidants.</p> <p>3 MR. CRAWFORD: Objection.</p> <p>4 Non-responsive.</p> <p>5 Q. Doctor, if you were going to offer</p> <p>6 the opinion in a court of law that polypropylene</p> <p>7 mesh was incompatible in the human body because</p> <p>8 of an MSDS sheet, in your opinion would that be</p> <p>9 relying on sound evidence-based medicine?</p> <p>10 MR. CRAWFORD: Objection to form.</p> <p>11 A. Absolutely not.</p> <p>12 Q. Doctor, are you familiar with a</p> <p>13 paper by Ashley King and Howard Goldman regarding</p> <p>14 whether or not polypropylene causes cancer or</p> <p>15 could be cytotoxic?</p> <p>16 A. Yes.</p> <p>17 Q. What did those authors conclude</p> <p>18 about whether or not that was a concern of</p> <p>19 polypropylene midurethral slings?</p> <p>20 A. So they concluded that there's</p> <p>21 absolutely no evidence in the medical literature</p> <p>22 that polypropylene slings are associated with a</p> <p>23 risk of malignancy.</p> <p>24 Q. And, Doctor, you were asked about</p> <p>25 chronic inflammatory responses, and I want to</p>	<p style="text-align: right;">Page 181</p> <p>1 you need to leave the mesh in place or it's not</p> <p>2 easily accessible, do you generally have any</p> <p>3 concerns, based on your experience and review of</p> <p>4 the literature and your review of patients, as to</p> <p>5 leaving mesh in that patient if they don't have</p> <p>6 any significant complaints?</p> <p>7 A. So, first of all, it is extremely</p> <p>8 rare in my experience and in the medical</p> <p>9 literature to have to remove mesh totally. And</p> <p>10 in my experience, patients who do present with</p> <p>11 pain after prolapse operations such as, you know,</p> <p>12 armed transobturator mesh systems, if you just</p> <p>13 relieve the tension on the mesh arm the pain will</p> <p>14 go away. Mesh itself does not cause pain, but it</p> <p>15 can cause pain where it inserts into the pelvic</p> <p>16 floor muscles. And there are techniques that</p> <p>17 have been described. In fact, one was described</p> <p>18 by one of my former fellows, and I've shown this</p> <p>19 in videos, of getting into the space of Retzius</p> <p>20 laparoscopically and just relieving the tension</p> <p>21 on the mesh arms and successfully treating women</p> <p>22 with pelvic pain.</p> <p>23 Q. And so would it be fair to say that</p> <p>24 you're able to successfully treat women who may</p> <p>25 have some pain after a mesh procedure without</p>

<p style="text-align: right;">Page 182</p> <p>1 performing significant dissection?</p> <p>2 A. Correct.</p> <p>3 Q. And in terms of severity of pain,</p> <p>4 is it an accurate statement that any mesh -- any</p> <p>5 patient who has mesh undergoes more severe pain</p> <p>6 or dyspareunia than a patient who had a native</p> <p>7 tissue repair for prolapse?</p> <p>8 MR. CRAWFORD: Objection to form.</p> <p>9 A. That is not true.</p> <p>10 Q. And is that based on your clinical</p> <p>11 experience, Doctor?</p> <p>12 A. That's based on my clinical</p> <p>13 experience, but it's also based on the</p> <p>14 literature, that patients with native tissue</p> <p>15 repairs can have significant pain. The one that</p> <p>16 comes to mind is posterior repairs went anywhere</p> <p>17 from 19 to 32 percent of women with undergoing</p> <p>18 levator plication can have significant</p> <p>19 dyspareunia, and there is -- so pain and</p> <p>20 dyspareunia can happen with any native tissue</p> <p>21 repair.</p> <p>22 Q. So would it be fair to say that</p> <p>23 pain and dyspareunia are not unique to mesh?</p> <p>24 A. That is correct.</p> <p>25 Q. And counsel asked you to look</p>	<p style="text-align: right;">Page 184</p> <p>1 chronic inflammatory response is not indicative</p> <p>2 or causally related to chronic pain?</p> <p>3 A. That is correct.</p> <p>4 Q. And, in fact, if you look at</p> <p>5 another study by two of plaintiffs' experts,</p> <p>6 Dr. Klosterhalfen and Dr. Uwe Klinge from 2002,</p> <p>7 what did they conclude in this paper about</p> <p>8 describing the long-term biocompatibility of</p> <p>9 surgical mesh?</p> <p>10 A. They concluded that long-term</p> <p>11 incorporation of polypropylene mesh in humans has</p> <p>12 a more favorable tissue response with increasing</p> <p>13 implantation interval.</p> <p>14 Q. And similar to the Hill article,</p> <p>15 what did Klosterhalfen and Klinge note about any</p> <p>16 correlation between an inflammatory response and</p> <p>17 chronic pain?</p> <p>18 MR. CRAWFORD: Objection to form.</p> <p>19 A. So they concluded that, and they</p> <p>20 mentioned it was striking that there was very</p> <p>21 little difference in inflammatory response in</p> <p>22 mesh removed for recurrence or for chronic pain.</p> <p>23 Q. And, Doctor, counsel asked you a</p> <p>24 number of questions about what specific internal</p> <p>25 documents can you recall reviewing off the top of</p>
<p style="text-align: right;">Page 183</p> <p>1 during a break for a study to support your</p> <p>2 opinion about inflammatory response and whether</p> <p>3 or not a chronic inflammatory response correlated</p> <p>4 to chronic pain. Could you just describe that</p> <p>5 article that you were able to find?</p> <p>6 A. Right. So this is an article by</p> <p>7 Audra, A-U-D-R-A, Jolyn, J-O-L-Y-N, Hill in the</p> <p>8 International Urogynecology Journal from 2015</p> <p>9 where they excised portions of mesh for both</p> <p>10 voiding dysfunction as well as pain and</p> <p>11 interestingly found that mesh excised for voiding</p> <p>12 dysfunction demonstrated elevated levels of</p> <p>13 inflammation compared to mesh that was excised</p> <p>14 for pain and/or exposure.</p> <p>15 Q. And what else did they conclude or</p> <p>16 how else did they summarize that?</p> <p>17 A. Well, basically in their summary</p> <p>18 they stated that vaginally placed midurethral</p> <p>19 slings that are excised for voiding dysfunction</p> <p>20 demonstrated elevated levels of inflammation</p> <p>21 compared to mesh that was excised for pain or</p> <p>22 exposure.</p> <p>23 Q. So does this study in addition to</p> <p>24 your clinical experience and review of other</p> <p>25 medical literature support your opinion that a</p>	<p style="text-align: right;">Page 185</p> <p>1 your head. Do you recall that?</p> <p>2 A. Yes.</p> <p>3 Q. Would it be fair to say that you</p> <p>4 showed up here with five banker's boxes worth of</p> <p>5 documents in addition to a flash drive that we'll</p> <p>6 provide to counsel?</p> <p>7 A. Yes.</p> <p>8 Q. And those would be materials that</p> <p>9 you reviewed in some shape or form?</p> <p>10 A. Yes.</p> <p>11 Q. And while you may not have been</p> <p>12 able to read every single word of every document,</p> <p>13 were you at least able to skim through to</p> <p>14 determine whether or not there was something that</p> <p>15 caught your eye --</p> <p>16 A. Yes.</p> <p>17 Q. -- that you wanted to read more</p> <p>18 closely?</p> <p>19 A. That's correct.</p> <p>20 Q. And, again, just -- I think I asked</p> <p>21 you about this, but I want to make sure. When</p> <p>22 you asked us to provide with the good and the</p> <p>23 bad, we did in fact provide you with the</p> <p>24 documents and literature referenced in the body</p> <p>25 of plaintiffs' expert reports, correct?</p>

<p style="text-align: right;">Page 186</p> <p>1 MR. CRAWFORD: Objection to form.</p> <p>2 A. That is correct.</p> <p>3 Q. Doctor, are all the opinions that</p> <p>4 you've offered in your expert report and today in</p> <p>5 your general TVT, Prolene®, Gynemesh® PS and</p> <p>6 Prolift deposition held to a reasonable degree of</p> <p>7 medical certainty?</p> <p>8 A. Yes, they are.</p> <p>9 MR. ROSENBLATT: I have no further</p> <p>10 questions at this time.</p> <p>11</p> <p>12 FURTHER EXAMINATION</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Doctor, you just testified</p> <p>15 regarding several studies, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And when you were testifying about</p> <p>18 those studies, you were reading from those</p> <p>19 studies, weren't you?</p> <p>20 A. Yes, I was.</p> <p>21 Q. Okay, I need to see them.</p> <p>22 Doctor, I've been handed a stack of</p> <p>23 studies that you were reading from in your</p> <p>24 testimony to questions asked by defense counsel</p> <p>25 just now; is that right?</p>	<p style="text-align: right;">Page 188</p> <p>1 on it, correct?</p> <p>2 A. Correct.</p> <p>3 Q. Are those the highlights you were</p> <p>4 reading from in your examination by defense</p> <p>5 counsel?</p> <p>6 A. Yes.</p> <p>7 Q. Did you put those highlights on</p> <p>8 there?</p> <p>9 A. I did not.</p> <p>10 Q. Who did?</p> <p>11 A. The counsel did, but I've read</p> <p>12 these articles myself.</p> <p>13 MR. CRAWFORD: Objection.</p> <p>14 Non-responsive. Move to strike after "counsel</p> <p>15 did."</p> <p>16 (Whereupon, Deposition Exhibit 8,</p> <p>17 "Histopathology of excised midurethral sling</p> <p>18 Mesh" by Hill, et al,</p> <p>19 was marked for identification.)</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. I'm going to show you what was</p> <p>22 marked as Exhibit No. 8.</p> <p>23 Do you recognize that as one of the</p> <p>24 studies you were reading from in your examination</p> <p>25 by defense counsel?</p>
<p style="text-align: right;">Page 187</p> <p>1 A. Yes.</p> <p>2 (Whereupon, Deposition Exhibit 7,</p> <p>3 "Influence of implantation Interval on the</p> <p>4 long-term biocompatibility of surgical mesh"</p> <p>5 by Klosterhalfen, et al,</p> <p>6 was marked for identification.)</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. In your examination by defense</p> <p>9 counsel, did you read from Exhibit No. 7?</p> <p>10 A. I did.</p> <p>11 Q. How would you describe that report?</p> <p>12 What's the name of that report?</p> <p>13 A. "Influence of implantation interval</p> <p>14 on the long-term biocompatibility of surgical</p> <p>15 mesh."</p> <p>16 Q. For purposes of time and economy,</p> <p>17 if you were talking to one of your colleagues,</p> <p>18 would you say this is the Klosterhalfen report?</p> <p>19 A. Yes --</p> <p>20 Q. Okay.</p> <p>21 A. -- but you know, you want to make</p> <p>22 sure because authors often write multiple papers,</p> <p>23 so you want to make sure you're referencing the</p> <p>24 right paper.</p> <p>25 Q. Okay. This document has highlights</p>	<p style="text-align: right;">Page 189</p> <p>1 A. Yes.</p> <p>2 Q. How would you describe it to one of</p> <p>3 your colleagues, that article?</p> <p>4 A. This is the Hill study about</p> <p>5 histopathology of excised midurethral sling mesh.</p> <p>6 Q. Does that exhibit have highlights</p> <p>7 on it?</p> <p>8 A. Yes, it does.</p> <p>9 Q. Did you make those highlights?</p> <p>10 A. On this particular copy, no.</p> <p>11 Q. Did you read from those highlights</p> <p>12 during your examination by defense counsel?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Who put those highlights on that</p> <p>15 document?</p> <p>16 A. Attorney Rosenblatt.</p> <p>17 Q. The lawyer for Ethicon?</p> <p>18 A. Yes.</p> <p>19 MR. ROSENBLATT: And, Counsel, I'll</p> <p>20 just represent I only had one copy, so I showed</p> <p>21 him my highlighted copy.</p> <p>22 (Whereupon, Deposition Exhibit 9,</p> <p>23 "Current Controversies Regarding Oncologic</p> <p>24 Risk Associated with Polypropylene</p> <p>25 Midurethral Slings" by King, et al,</p>

<p style="text-align: right;">Page 190</p> <p>1 was marked for identification.)</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. Do you recognize the exhibit marked</p> <p>4 as -- strike that.</p> <p>5 Do you recognize the document</p> <p>6 marked as Exhibit No. 9?</p> <p>7 A. Yes.</p> <p>8 Q. Is that a study you were referring</p> <p>9 to in your examination by defense counsel?</p> <p>10 A. Yes.</p> <p>11 Q. How would you describe that study</p> <p>12 to one of your colleagues?</p> <p>13 A. This is a study by -- the first</p> <p>14 author is King, and it's "Current Controversies</p> <p>15 Regarding Oncologic Risk Associated with</p> <p>16 Polypropylene Midurethral Slings."</p> <p>17 Q. Does that document have highlights</p> <p>18 on it?</p> <p>19 A. Yes, it does.</p> <p>20 Q. Did you read from those highlights</p> <p>21 during your examination by defense counsel?</p> <p>22 A. I did.</p> <p>23 Q. Who put those highlights on that</p> <p>24 document?</p> <p>25 A. Attorney Rosenblatt.</p>	<p style="text-align: right;">Page 192</p> <p>1 Q. Is that the attorney for Ethicon?</p> <p>2 A. Yes.</p> <p>3 (Whereupon, Deposition Exhibit 11,</p> <p>4 "Long-Term Results of Burch Colposuspension"</p> <p>5 by Demirci, was marked</p> <p>6 for identification.)</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. Do you recognize the document</p> <p>9 marked as Exhibit No. 10?</p> <p>10 A. Yes.</p> <p>11 Q. How would you --</p> <p>12 MR. ROSENBLATT: Just, Counsel, I</p> <p>13 think that says 11 there.</p> <p>14 MR. CRAWFORD: I'm sorry. Thank</p> <p>15 you.</p> <p>16 Do you recognize the document</p> <p>17 marked as Exhibit No. 11?</p> <p>18 A. Yes.</p> <p>19 Q. How would you describe that</p> <p>20 document to one of your colleagues?</p> <p>21 A. The first author is Demirci,</p> <p>22 D-E-M-I-R-C-I, and it's "Long-Term Results of</p> <p>23 Burch Colposuspension."</p> <p>24 Q. Did you read from that document</p> <p>25 during your examination by defense counsel?</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. The attorney for Ethicon?</p> <p>2 A. Yes.</p> <p>3 (Whereupon, Deposition Exhibit 10,</p> <p>4 "Polypropylene as a reinforcement in pelvic</p> <p>5 surgery is not inert: comparative analysis</p> <p>6 of 100 explants" by Clavé,</p> <p>7 was marked for identification.)</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Do you recognize the document</p> <p>10 marked as Exhibit No. 10?</p> <p>11 A. Yes.</p> <p>12 Q. How would you describe that</p> <p>13 document to one of your colleagues?</p> <p>14 A. This is the Clavé article about</p> <p>15 polypropylene as a reinforcement in pelvic</p> <p>16 surgery is not inert.</p> <p>17 Q. Does that document have highlights</p> <p>18 on it?</p> <p>19 A. It does.</p> <p>20 Q. Did you read from those highlights</p> <p>21 during your examination by defense counsel?</p> <p>22 A. I did.</p> <p>23 Q. And who put those highlights on</p> <p>24 that document?</p> <p>25 A. Attorney Rosenblatt.</p>	<p style="text-align: right;">Page 193</p> <p>1 A. Yes.</p> <p>2 Q. Did you read the highlighted</p> <p>3 portions?</p> <p>4 A. I did.</p> <p>5 Q. And who put those highlights there?</p> <p>6 A. Attorney Rosenblatt.</p> <p>7 Q. Is that the attorney representing</p> <p>8 Ethicon?</p> <p>9 A. Yes.</p> <p>10 (Whereupon, Deposition Exhibit 12,</p> <p>11 "Biocompatibility of prosthetic meshes in</p> <p>12 abdominal surgery" by Binnebösel,</p> <p>13 was marked for identification.)</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Do you recognize the document</p> <p>16 marked as Exhibit No. 12?</p> <p>17 A. Yes.</p> <p>18 Q. How would you describe that</p> <p>19 document to one of your colleagues?</p> <p>20 A. The first author is Binnebösel, and</p> <p>21 it's entitled "Biocompatibility of prosthetic</p> <p>22 meshes in abdominal surgery."</p> <p>23 Q. Is that document highlighted?</p> <p>24 A. Yes.</p> <p>25 Q. Did you read from those highlights</p>

<p style="text-align: right;">Page 194</p> <p>1 during your examination by defense counsel?</p> <p>2 A. I did.</p> <p>3 Q. Who put those highlights on that</p> <p>4 document?</p> <p>5 A. Attorney Rosenblatt.</p> <p>6 Q. Is that the lawyer representing</p> <p>7 Ethicon?</p> <p>8 A. It still is.</p> <p>9 (Whereupon, Deposition Exhibit 13,</p> <p>10 "Does the tension-free vaginal tape stay</p> <p>11 where you put it?" by Dietz,</p> <p>12 was marked for identification.)</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Do you recognize the document</p> <p>15 marked as Exhibit No. 13?</p> <p>16 A. Yes.</p> <p>17 Q. How would you describe that</p> <p>18 document to one of your colleagues?</p> <p>19 A. That's the article by Dr. Dietz on</p> <p>20 "Does the tension-free vaginal tape stay where</p> <p>21 you put it?"</p> <p>22 Q. Does that document have highlights</p> <p>23 on it?</p> <p>24 A. It does.</p> <p>25 Q. Did you read from those highlights</p>	<p style="text-align: right;">Page 196</p> <p>1 A. It does.</p> <p>2 Q. Did you read from those highlights</p> <p>3 during your examination by defense counsel?</p> <p>4 A. I did.</p> <p>5 Q. Who put those highlights on that</p> <p>6 document?</p> <p>7 A. Attorney Rosenblatt.</p> <p>8 Q. Is that one of the attorneys</p> <p>9 representing Ethicon in this case?</p> <p>10 A. Yes.</p> <p>11 (Whereupon, Deposition Exhibit 15,</p> <p>12 "Mesh contraction: myth or reality?"</p> <p>13 by Dietz, et al,</p> <p>14 was marked for identification.)</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Do you recognize the document</p> <p>17 marked as Exhibit No. 15 to your deposition?</p> <p>18 A. Yes.</p> <p>19 Q. How would you describe that</p> <p>20 document to one of your colleagues?</p> <p>21 A. So that's another article by</p> <p>22 Dr. Dietz, and it's "Mesh Contraction: myth or</p> <p>23 reality?"</p> <p>24 Q. And does that document have</p> <p>25 highlights on it?</p>
<p style="text-align: right;">Page 195</p> <p>1 during your examination by defense counsel?</p> <p>2 A. I did.</p> <p>3 Q. Who put those highlights on that</p> <p>4 document?</p> <p>5 A. Attorney Rosenblatt.</p> <p>6 Q. Is that the attorney for Ethicon in</p> <p>7 this case?</p> <p>8 A. Correct.</p> <p>9 (Whereupon, Deposition Exhibit 14,</p> <p>10 "Ultrasound Assessment of Mid-Urethra Tape</p> <p>11 at Three-Year Follow-Up after Tension-Free</p> <p>12 Vaginal Tape Procedure" by Lo, et al,</p> <p>13 was marked for identification.)</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Do you recognize the document</p> <p>16 that's been marked as Exhibit No. 14 to your</p> <p>17 deposition?</p> <p>18 A. Yes.</p> <p>19 Q. How would you describe that</p> <p>20 document to one of your colleagues?</p> <p>21 A. The first author is Lo, L-O, and</p> <p>22 it's "Ultrasound Assessment of Mid-Urethra Tape</p> <p>23 at Three-Year Follow-Up After TVT Procedure."</p> <p>24 Q. Does that document have highlights</p> <p>25 on it?</p>	<p style="text-align: right;">Page 197</p> <p>1 A. It does.</p> <p>2 Q. Did you read from those highlights</p> <p>3 during your examination by defense counsel?</p> <p>4 A. Yes, I did.</p> <p>5 Q. Who put those highlights on that</p> <p>6 document?</p> <p>7 A. Attorney Rosenblatt.</p> <p>8 Q. Is that the lawyer for Ethicon in</p> <p>9 this case?</p> <p>10 A. It is.</p> <p>11 (Whereupon, Deposition Exhibit 16,</p> <p>12 "Basic science and clinical aspects of mesh</p> <p>13 infection in pelvic floor reconstructive</p> <p>14 surgery" by de Tayrac, et al,</p> <p>15 was marked for identification.)</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. Do you see the document marked as</p> <p>18 Exhibit No. 16 to your deposition?</p> <p>19 A. Yes.</p> <p>20 Q. How would you describe that</p> <p>21 document to one of your colleagues.</p> <p>22 A. This is an article by de Tayrac,</p> <p>23 D-E T-A-Y-R-A-C, and it's entitled "Basic signs</p> <p>24 and clinical aspects of mesh infection in pelvic</p> <p>25 floor reconstructive surgery."</p>

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<p>1 Q. Is that document highlighted?</p> <p>2 A. Yes.</p> <p>3 Q. Did you read from those highlights</p> <p>4 during your examination by defense counsel?</p> <p>5 A. I did.</p> <p>6 Q. Who highlighted that document?</p> <p>7 A. Attorney Rosenblatt.</p> <p>8 Q. Is that the attorney representing</p> <p>9 Ethicon in this case?</p> <p>10 A. Yes.</p> <p>11 (Whereupon, Deposition Exhibit 17,</p> <p>12 "The Myth: In Vivo Degradation of</p> <p>13 Polypropylene Meshes" by Ong et al,</p> <p>14 was marked for identification.)</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Do you recognize the document</p> <p>17 marked as Exhibit No. 17 to your deposition?</p> <p>18 A. I do.</p> <p>19 Q. How would you describe that</p> <p>20 document to your colleagues?</p> <p>21 A. That is an article -- an abstract</p> <p>22 by Ong, O-N-G, and it's entitled "The Myth: In</p> <p>23 Vivo Degradation of Polypropylene Meshes."</p> <p>24 Q. Is that document highlighted?</p> <p>25 A. It is.</p>	<p>1 From Commercial Prolapse Kits."</p> <p>2 Q. Is that document highlighted?</p> <p>3 A. It is.</p> <p>4 Q. Did you read from those highlights</p> <p>5 during your examination by defense counsel?</p> <p>6 A. I did.</p> <p>7 Q. Who highlighted that document?</p> <p>8 A. Attorney Rosenblatt.</p> <p>9 Q. Is that the attorney for Ethicon in</p> <p>10 this case?</p> <p>11 A. Yes.</p> <p>12 (Whereupon, Deposition Exhibit 19,</p> <p>13 Material Safety Data Sheet for</p> <p>14 polypropylene, was marked</p> <p>15 for identification.)</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. Do you recognize the document</p> <p>18 marked as Exhibit No. 19?</p> <p>19 A. Yes.</p> <p>20 Q. What is that?</p> <p>21 A. This is the MSDS for polypropylene.</p> <p>22 (Whereupon, Deposition Exhibit 20,</p> <p>23 "Frequently Asked Questions by Providers</p> <p>24 Mid-urethral Slings for Stress Urinary</p> <p>25 Incontinence, was marked</p>
Page 199	Page 201
<p>1 Q. Did you read from those highlights</p> <p>2 during your examination by defense counsel?</p> <p>3 A. I did.</p> <p>4 Q. Who highlighted that document?</p> <p>5 A. Attorney Rosenblatt.</p> <p>6 Q. Is that the attorney representing</p> <p>7 Ethicon in this case?</p> <p>8 A. Yes.</p> <p>9 (Whereupon, Deposition Exhibit 18,</p> <p>10 "Purely Transvaginal/Perineal Management of</p> <p>11 Complications From Commercial Prolapse Kits</p> <p>12 Using a New Prostheses/Grafts Complication</p> <p>13 Classification System" by Firooz, et al,</p> <p>14 was marked for identification.)</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Do you recognize document number --</p> <p>17 excuse me.</p> <p>18 Do you recognize the document</p> <p>19 marked as Exhibit No. 18 to your deposition?</p> <p>20 A. Yes.</p> <p>21 Q. How would you describe that</p> <p>22 document to one of your colleagues?</p> <p>23 A. This is by first author Firoozi,</p> <p>24 F-I-R-O-O-Z-I, and it's entitled "Purely</p> <p>25 Transvaginal/Perineal Management of Complications</p>	<p>1 for identification.)</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. Okay. Do you recognize the</p> <p>4 document marked as Exhibit No. 20 to your</p> <p>5 deposition?</p> <p>6 A. Yes.</p> <p>7 Q. Do you recognize that document?</p> <p>8 A. Yes.</p> <p>9 Q. All right. How would you describe</p> <p>10 that document to one of your colleagues?</p> <p>11 A. This is the Frequently Asked</p> <p>12 Questions by Providers regarding midurethral</p> <p>13 slings that is from AUGS and SUFU, A-U-G-S and</p> <p>14 S-U-F-U.</p> <p>15 Q. Is that document highlighted?</p> <p>16 A. Yes.</p> <p>17 Q. Did you read from those highlights</p> <p>18 during your deposition?</p> <p>19 A. Yes.</p> <p>20 Q. And who highlighted that document?</p> <p>21 A. Attorney Rosenblatt.</p> <p>22 Q. Is that one of the attorneys</p> <p>23 representing Ethicon in this case?</p> <p>24 A. Yes.</p> <p>25 Q. Exhibit Nos. 7 through 20 all</p>

<p style="text-align: right;">Page 202</p> <p>1 documents that were highlighted by defense 2 counsel handed to you which you read from in your 3 deposition, are these all materials that were 4 provided to you by Butler Snow, the law firm 5 representing Ethicon in this case, when you were 6 first hired --</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 Q. -- as an expert witness?</p> <p>9 A. I can't tell you how many, but many 10 of those are articles that I had already pulled 11 myself.</p> <p>12 Q. Are any of Exhibits No. 7 through 13 20 materials that were provided to you by defense 14 counsel Butler Snow when you were retained or in 15 conjunction with your retainment by them for 16 expert witness testimony in this case?</p> <p>17 MR. ROSENBLATT: Objection, asked 18 and answered.</p> <p>19 A. I thought I answered that.</p> <p>20 Q. One more time.</p> <p>21 A. Some of them I've already seen, but 22 those were just handed to me, but I'm familiar 23 with all of those.</p> <p>24 Q. So you're telling me that you've 25 seen them before. I'm asking you were they given</p>	<p style="text-align: right;">Page 204</p> <p>1 Exhibits 7 through 20 included in your reliance 2 list?</p> <p>3 A. I would have to check, and the 4 reason I say that is -- can I take a look for a 5 minute?</p> <p>6 Q. Sure.</p> <p>7 A. The one in particular that I 8 believe is not -- that I know is not in my 9 reliance list, at least I don't think so, is the 10 abstract from the IUGA meeting which has taken 11 place yet. So it was provided recently because 12 the abstracts were recently, you know, published 13 in the International Urogynecology Journal.</p> <p>14 Q. One of these articles that's 15 contained in Exhibits No. 7 through 20 was an 16 article I'd asked you for during my examination 17 of you, and you said that you'd check on one of 18 the breaks and you'd get it for me and bring it 19 to me, correct?</p> <p>20 A. Correct.</p> <p>21 Q. We came back from break and you 22 provided it, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Did you find it yourself or did 25 defense counsel find it for you?</p>
<p style="text-align: right;">Page 203</p> <p>1 to you by Butler Snow in the materials that 2 Butler Snow provided to you shortly after you 3 were hired by them as an expert witness in this 4 case?</p> <p>5 MR. ROSENBLATT: Object to form. 6 Mischaracterizes the testimony, asked and 7 answered.</p> <p>8 A. What I'm trying to say is that, and 9 I can go through each one of them, but many of 10 them I was already familiar with before they were 11 provided to me by Butler Snow.</p> <p>12 Q. I understand, but were they all 13 provided to you by Butler Snow regardless of 14 whether you were familiar with them?</p> <p>15 MR. ROSENBLATT: Object to form. 16 You mean in addition to him having them himself?</p> <p>17 MR. CRAWFORD: Yes, sir.</p> <p>18 A. In addition to me having them 19 myself, they were also given to me by Butler 20 Snow.</p> <p>21 Q. The copies that were sent to you by 22 Butler Snow, were they highlighted?</p> <p>23 A. No. No documents from Butler Snow 24 were highlighted before they got to me.</p> <p>25 Q. Are all of these documents marked</p>	<p style="text-align: right;">Page 205</p> <p>1 A. Defense counsel found it 'cause I 2 couldn't find it in my own, but I know it's 3 there. It's in one of these banker's boxes.</p> <p>4 Q. And then he highlighted it for you, 5 right?</p> <p>6 A. Yes, I think to save time.</p> <p>7 MR. ROSENBLATT: Object to form. 8 That was the only copy. For efficiency sake, I 9 printed one copy.</p> <p>10 Q. You testified that you reviewed and 11 considered materials that are cited in 12 Dr. Rosenzweig's report, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know which ones?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 A. No, it's been quite a while. I'd 17 have to go back and look at it.</p> <p>18 Q. If you look at it, can you tell us?</p> <p>19 A. Is this it?</p> <p>20 Q. That's a good question. This one 21 is it.</p> <p>22 A. Okay. Thank you. Ask me what the 23 question was again.</p> <p>24 Q. Well, you've indicated that you've 25 reviewed materials that were attached to</p>

<p style="text-align: right;">Page 206</p> <p>1 Dr. Rosenzweig's report, and I want to know which 2 of those materials that are attached to 3 Dr. Rosenzweig's report have you reviewed? 4 A. Not exclusively, but I'm just 5 telling you which ones I recognize that I've 6 reviewed. Clavé, which we talked about, that 7 polypropylene as a reinforcement in pelvic 8 surgery is not inert. I believe that the Coda, 9 C-O-D-A, article. I believe that's in my 10 reliance report. There are others as well. I 11 would have to do the cross-reference to see if 12 they are in my reliance report, but I'm aware of 13 these articles. 14 Q. Well, I know that -- is there a 15 difference between being aware of the articles 16 and reviewing the articles? 17 A. No, I have. I have reviewed. I 18 can't say that I reviewed 100 percent of these, 19 but ones I thought were important I looked at. 20 I know I've seen articles by 21 K-L-I-N-G-E, Kling or Klingy. I don't know which 22 one of these I've looked at, but I have seen 23 those articles. 24 Q. I know it's late. I know we've 25 been on for a long time.</p>	<p style="text-align: right;">Page 208</p> <p>1 A. Correct. 2 Q. You have also been approached by 3 other medical device manufacturers and asked to 4 teach about their products, correct? 5 A. I have been, yes. 6 Q. And there's other products that are 7 manufactured by other manufacturers that you 8 either didn't believe in or weren't compelled to 9 teach because either you don't use them or you 10 just aren't that crazy about the product; is that 11 fair to say? 12 A. Well, if I'm not crazy about a 13 product, I won't use it. 14 Q. And you won't teach it? 15 A. And I won't teach it. 16 Q. What manufacturers have approached 17 you about -- asking you to teach about their 18 products that you've declined? 19 A. Caldera, for instance. 20 Q. What device? 21 A. Their slings. 22 Q. Okay. 23 A. Mentor approached me years ago 24 about ObTape which I was not pleased with. 25 Q. And who was that? I'm sorry.</p>
<p style="text-align: right;">Page 207</p> <p>1 A. No, I'm okay. Thank you. 2 Q. And I promise I'm not picking on 3 you. And I'll be completely candid with you, I 4 expect to hear something to the tune of 5 Dr. Rosenzweig not only reviewed all the 6 materials in his report but he also, in 7 criticizing Dr. Rosenzweig, has reviewed all of 8 the stuff Dr. Rosenzweig has reviewed. And if 9 that's not true, I need to know, and that's why I 10 need to know what you've -- what is attached to 11 Dr. Rosenzweig's report that you've reviewed. 12 A. So I think, in my mind, the 13 important thing is I've reviewed Dr. Rosenzweig's 14 report. He references those other reports. Have 15 I read every one of those other reports, 16 absolutely not, but I know what's contained. 17 What he's doing is summarizing what's in those 18 reports in his report. And I would not expect 19 him to fabricate anything, so I take it at face 20 value his opinions are based on those reports. 21 Q. That will do. We'll move on. 22 Thank you. 23 Ethicon approached you to teach 24 students or other doctors about Ethicon products, 25 correct?</p>	<p style="text-align: right;">Page 209</p> <p>1 A. Mentor, M-E-N-T-O-R. I've been 2 asked about teaching for AMS when they had 3 Elevate, and I declined. Those are the ones that 4 come to mind. 5 Q. Why did you decline Caldera's offer 6 to teach others how to use their slings? 7 A. Only in that I wasn't using their 8 slings, and there was nothing particularly wrong 9 with their sling, but I wasn't using it. 10 Q. Why did you decline Mentor's 11 request to teach others how to use their tape? 12 A. I did not like the characteristics, 13 the physical characteristics, of their tape. 14 Q. What about it did you not like? 15 A. It was a multifilament microporous 16 tape that didn't have the characteristics of a 17 Type 1 polypropylene monofilament that we talked 18 about earlier. 19 Q. Did the microporous nature of the 20 tape turn you off for lack of a better term? 21 A. Yes. 22 Q. Why? 23 A. Because of the risk of infection 24 and lack of incorporation into the tissues. 25 Q. Anything else about the Mentor tape</p>

<p style="text-align: right;">Page 210</p> <p>1 that you didn't like?</p> <p>2 A. There were already reports of</p> <p>3 exposures and erosions, and I didn't feel like it</p> <p>4 was something that I wanted to get involved in.</p> <p>5 Q. Why did you decline AMS's request</p> <p>6 to teach others how to use their Elevate®</p> <p>7 product?</p> <p>8 A. No other reason than that I was</p> <p>9 using a comparable product from Boston Scientific</p> <p>10 at that point and was very pleased with the way</p> <p>11 it worked on, and I just wasn't -- I had tried</p> <p>12 the Elevate® product a couple times, and I</p> <p>13 thought it was fine, but I just wasn't using it,</p> <p>14 and I didn't think it was right to teach</p> <p>15 something I wasn't using.</p> <p>16 Q. Regarding teaching other doctors</p> <p>17 how to use Ethicon products, you testified that</p> <p>18 while you were doing it for the love of</p> <p>19 teaching -- strike it.</p> <p>20 Regarding teaching other doctors</p> <p>21 how to use Ethicon products, you've testified</p> <p>22 that you were doing that for the love of</p> <p>23 teaching, not for the money, true?</p> <p>24 A. I could make just as much from my</p> <p>25 practice by staying, you know, at home and seeing</p>	<p style="text-align: right;">Page 212</p> <p>1 A. I don't know.</p> <p>2 Q. More than five?</p> <p>3 A. Well, I think it -- I think it had</p> <p>4 a term on it of maybe a year or maybe two years,</p> <p>5 and so when that was up, I was sent a new</p> <p>6 consulting agreement.</p> <p>7 Q. And for how many years?</p> <p>8 A. I'm going to guess it started</p> <p>9 around the year 2000, and I do not remember the</p> <p>10 last year that I signed a consulting agreement,</p> <p>11 but it's got to be at least five years ago.</p> <p>12 Q. Five years ago from today would be</p> <p>13 2011, correct?</p> <p>14 A. Yeah, but that's a rough estimate.</p> <p>15 I really don't know.</p> <p>16 Q. I totally understand we're dealing</p> <p>17 with a rough estimate --</p> <p>18 A. Yeah.</p> <p>19 Q. -- but if you started around 2000</p> <p>20 and ended in 2011, you were under consulting</p> <p>21 agreements with Ethicon for approximately 11</p> <p>22 years.</p> <p>23 A. I think that's about right.</p> <p>24 Q. And I'll rephrase the question.</p> <p>25 For approximately 11 years from</p>
<p style="text-align: right;">Page 211</p> <p>1 patients and doing surgery, that's correct.</p> <p>2 Q. You testified that you were doing</p> <p>3 it for the love of the product, not the money.</p> <p>4 Is that true?</p> <p>5 MR. ROSENBLATT: Object to form.</p> <p>6 Asked and answered.</p> <p>7 A. Right. I think I actually said for</p> <p>8 the love of teaching and teaching products that I</p> <p>9 was using.</p> <p>10 Q. Nevertheless, Ethicon paid you?</p> <p>11 A. They compensated me.</p> <p>12 Q. How much were you compensated by</p> <p>13 Ethicon for teaching others how to use their</p> <p>14 products?</p> <p>15 A. I don't remember, but it was in</p> <p>16 line with what everyone else was getting. As far</p> <p>17 as I knew, it was fair market value for teaching.</p> <p>18 Q. What was everybody else getting?</p> <p>19 A. You know, I don't remember 'cause</p> <p>20 it was over a span of many years, but there were</p> <p>21 consulting agreements that spelled out what I was</p> <p>22 making.</p> <p>23 Q. How many different consulting</p> <p>24 agreements have you entered into with Ethicon</p> <p>25 concerning teaching their products?</p>	<p style="text-align: right;">Page 213</p> <p>1 about year 2000 to around 2011 you were under</p> <p>2 consulting agreements with Ethicon concerning</p> <p>3 teaching others how to use their products?</p> <p>4 A. Correct.</p> <p>5 Q. But as you sit here today under</p> <p>6 oath as an expert witness in this case involving</p> <p>7 Ethicon, you cannot recall the compensation rate</p> <p>8 for any of the consulting agreements you entered</p> <p>9 into with Ethicon between the year 2000 and 2011?</p> <p>10 MR. CRAWFORD: Object to form.</p> <p>11 Asked and answered.</p> <p>12 A. So I would be guessing which I</p> <p>13 don't want to do but if -- and I'd be happy if --</p> <p>14 if my counsel wants me to guess, I'd be happy to</p> <p>15 guess.</p> <p>16 MR. ROSENBLATT: I'd prefer if you</p> <p>17 did not guess.</p> <p>18 Q. I'd prefer for you to estimate,</p> <p>19 kind of like you estimated that your last</p> <p>20 consulting agreement with Ethicon was about five</p> <p>21 years ago. Estimate for me about how much were</p> <p>22 the consulting agreements?</p> <p>23 MR. CRAWFORD: Object to form.</p> <p>24 Asked and answered, asking the witness to</p> <p>25 speculate. If you can provide a reliable</p>

<p style="text-align: right;">Page 214</p> <p>1 estimate, you can do so.</p> <p>2 A. My best guess would be that a day</p> <p>3 of consulting was probably \$2,000 dollars to</p> <p>4 \$2,500.</p> <p>5 Q. Did that remain the same from 2000</p> <p>6 to 2011?</p> <p>7 A. I don't remember.</p> <p>8 Q. How many days a month were you</p> <p>9 consulting for Ethicon?</p> <p>10 MR. ROSENBLATT: Object to form.</p> <p>11 A. I really do not remember.</p> <p>12 Q. Do you have an estimate?</p> <p>13 A. It was -- I don't even think it was</p> <p>14 number of days per month. It was probably number</p> <p>15 of days per year. You know, maybe there were six</p> <p>16 courses, maybe there were ten.</p> <p>17 Q. How many days would a course last?</p> <p>18 A. I think it varied, but it was never</p> <p>19 more than two. It was usually one.</p> <p>20 Q. One to two days each course?</p> <p>21 A. Correct.</p> <p>22 Q. Again, we're using estimates here.</p> <p>23 A. Yeah.</p> <p>24 Q. And to summarize, you were involved</p> <p>25 in consulting agreements with Ethicon for</p>	<p style="text-align: right;">Page 216</p> <p>1 consulting agreements?</p> <p>2 A. I believe -- I probably have kept</p> <p>3 the last one. I may have others.</p> <p>4 Q. If you were going to retain an</p> <p>5 Ethicon consulting agreement, where would you</p> <p>6 keep it?</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 Counsel, I think those would have all been</p> <p>9 produced in the general Ethicon production.</p> <p>10 Q. Would they be at your office?</p> <p>11 A. They'd either be in my office or in</p> <p>12 my home.</p> <p>13 Q. How much do you charge per day to</p> <p>14 testify for Ethicon?</p> <p>15 A. I think it's listed in my report.</p> <p>16 So it's \$9,000 a day and a day is considered any</p> <p>17 more than three hours which includes traveling</p> <p>18 time.</p> <p>19 Q. Your deposition was scheduled to</p> <p>20 start today at 9 a.m., correct?</p> <p>21 A. Correct.</p> <p>22 Q. And we got started at about that</p> <p>23 time, right?</p> <p>24 A. (Witness nods.)</p> <p>25 Q. Right?</p>
<p style="text-align: right;">Page 215</p> <p>1 approximately 11 years from 2000 to 2011,</p> <p>2 correct?</p> <p>3 A. Correct.</p> <p>4 Q. You're estimating you were</p> <p>5 compensated approximately \$2,000 per day for each</p> <p>6 day of consulting, correct?</p> <p>7 A. I think I said between 2,000 and</p> <p>8 2,500.</p> <p>9 Q. You would teach approximately six</p> <p>10 to ten courses per year --</p> <p>11 MR. ROSENBLATT: I object to form.</p> <p>12 Q. -- is that right?</p> <p>13 MR. ROSENBLATT: Assumes facts not</p> <p>14 in evidence.</p> <p>15 A. Yeah, I wish I could be more</p> <p>16 precise. It may have been less, and it may have</p> <p>17 been more, and it varied per year.</p> <p>18 Q. That's why you're estimating a</p> <p>19 range which is approximately six to ten courses</p> <p>20 per year; is that right?</p> <p>21 A. Yeah, the best I can recall, yes.</p> <p>22 Q. Each course would last between one</p> <p>23 to two days but no more than two days?</p> <p>24 A. Correct.</p> <p>25 Q. Did you keep any of those</p>	<p style="text-align: right;">Page 217</p> <p>1 A. Correct.</p> <p>2 Q. And it's 3 o'clock now, correct?</p> <p>3 A. Correct.</p> <p>4 Q. So you're in excess of the three</p> <p>5 hour minimum, right?</p> <p>6 A. Correct.</p> <p>7 Q. So we're in the \$9,000 range today,</p> <p>8 correct?</p> <p>9 A. Correct.</p> <p>10 Q. You expect to be compensated \$9,000</p> <p>11 for your testimony at this deposition today --</p> <p>12 A. Correct.</p> <p>13 Q. -- which is taking place at the</p> <p>14 Courtyard by Marriott located at 777 Memorial</p> <p>15 Drive in Cambridge, Massachusetts?</p> <p>16 A. Correct.</p> <p>17 Q. Did you also charge for review of</p> <p>18 materials in preparation for this deposition?</p> <p>19 A. I haven't yet but yes.</p> <p>20 Q. How long did you spend reviewing</p> <p>21 materials for this deposition that you'll charge</p> <p>22 for?</p> <p>23 MR. ROSENBLATT: I was just going</p> <p>24 to say to the best of your recollection.</p> <p>25 A. Yeah, I don't have it in front of</p>

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1 me, but if I had to guess, my best estimate would
 2 probably be in the, you know, 20-hour range.
 3 Q. How much do you charge for
 4 reviewing documents in preparation for this
 5 deposition?
 6 A. \$800 an hour.
 7 Q. Did you charge for your meeting
 8 with defense counsel prior to walking into the
 9 deposition this morning?
 10 A. You mean this morning?
 11 Q. Yes, sir.
 12 A. No, that's part of the \$9,000 per
 13 day.
 14 Q. Did you come from out of town
 15 today?
 16 A. I live about 20 minutes from here.
 17 Q. See, I couldn't remember. So
 18 that's a no. You didn't stay at the Courtyard
 19 last night, did you?
 20 A. It's a different town. It's out of
 21 town.
 22 Q. Is it far enough to get a per diem
 23 payment?
 24 A. No.
 25 Q. So if you've got \$9,000 for your

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1 deposition time today plus \$800 per year for 20
 2 hours of depo prep time, that would be \$16,000.
 3 \$800 per hour for 20 hours is
 4 \$16,000 charged for your records review in
 5 preparation for this deposition.
 6 A. Correct.
 7 Q. Plus there's \$9,000 for the actual
 8 deposition time, correct?
 9 A. Correct.
 10 Q. So that's a \$25,000 charge for the
 11 work you've done in preparation for this
 12 deposition today?
 13 A. Correct.
 14 Q. This deposition lasted
 15 approximately six hours?
 16 A. If you do the math, I believe you.
 17 Q. Well, we're not quite done, but
 18 let's say from -- if we started at 9 a.m. and we
 19 end right now at approximately 3 p.m., that would
 20 be approximately six hours, correct?
 21 A. Yes.
 22 Q. Your report that's been marked as
 23 an exhibit to your deposition today, that's your
 24 general causation report, correct?
 25 A. Yes.

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1 Q. When you submitted that report to
 2 Butler Snow, it was in a different font than what
 3 it's in right now; is that right?
 4 A. Yeah, when I say different font, I
 5 think it might have been just -- again, I think
 6 it was the line spacing. That's why I just
 7 wanted to make sure it was mine that you were
 8 handing me.
 9 Q. Do you know who modified that
 10 report between the time you submitted it to
 11 Butler Snow and today?
 12 A. When you say "modified," it was
 13 just a change in the format. There's no changes
 14 in the language or the words. And do I know who
 15 did that --
 16 Q. Yes, sir.
 17 A. -- no, I don't.
 18 MR. ROSENBLATT: Counsel, I'll
 19 represent that I double spaced his report, and I
 20 put the cover page on there with the case heading
 21 because I don't think Dr. Rosenblatt really knew
 22 how to format that first page.
 23 MR. CRAWFORD: Thank you, Paul.
 24 One of the exhibits to your
 25 deposition is a document related to AUGS; is that

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1 correct.
 2 A. The one that we just read a little
 3 while ago?
 4 Q. Yes, sir.
 5 A. Yes.
 6 Q. In fact, it's Exhibit No. 20 to
 7 your deposition, correct?
 8 A. Yes.
 9 Q. What is AUGS?
 10 A. AUGS is the American Urogynecologic
 11 Society.
 12 Q. In 2013, AUGS released a position
 13 statement on surgical options for pelvic floor
 14 disorders; is that right?
 15 A. Yes.
 16 Q. Can you summarize what AUGS said in
 17 2013 as it relates to surgical options for pelvic
 18 floor disorders?
 19 A. I mean, there have been several
 20 position statements that AUGS has released, and I
 21 think the one you're referring to is -- well,
 22 there are several. There was one that had to do
 23 with midurethral slings for stress incontinence,
 24 and the other one that I recall is the one that
 25 had to do with limiting, you know, limiting

<p style="text-align: right;">Page 222</p> <p>1 options for pelvic floor reconstruction.</p> <p>2 Q. What is your understanding as far</p> <p>3 as AUGS position on transvaginal mesh used for</p> <p>4 midurethral slings?</p> <p>5 A. Right. So what the position</p> <p>6 statement was saying for that was that, you know,</p> <p>7 slings have become the gold standard, that</p> <p>8 they've been used in millions of women with great</p> <p>9 success and that it was not the intention of the</p> <p>10 FDA to limit the use of suburethral slings and</p> <p>11 that it was a very important procedure for stress</p> <p>12 incontinence.</p> <p>13 Q. Is it fair to say that AUGS</p> <p>14 advocates the use of transvaginal mesh for --</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 Q. -- stress urinary incontinence</p> <p>17 repairs?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 A. Yeah, I'm not sure I'd use the word</p> <p>20 advocates. I don't mean to be splitting hairs,</p> <p>21 but it is a very important device that the</p> <p>22 overwhelming majority of AUGS members which</p> <p>23 represent the primary surgeons in the country</p> <p>24 from a, you know, urogynecologic standpoint who</p> <p>25 take care of women who have stress incontinence,</p>	<p style="text-align: right;">Page 224</p> <p>1 Q. Who elects you? Who elects the</p> <p>2 board members?</p> <p>3 A. I think names are brought up that</p> <p>4 are nominated, and then the society itself will</p> <p>5 vote on the board members.</p> <p>6 Q. You've been on the board of</p> <p>7 directors for AUGS?</p> <p>8 A. Yes.</p> <p>9 Q. What years did you serve on the</p> <p>10 AUGS board of directors?</p> <p>11 A. Do you have my CV? I believe it</p> <p>12 was -- 2012 to 2014, I believe. In that time</p> <p>13 frame.</p> <p>14 Q. So you were on the AUGS board of</p> <p>15 directors when the 2013 position statement was</p> <p>16 issued, correct?</p> <p>17 A. I was, but I was not part of that.</p> <p>18 I completely support it, but I was not part of</p> <p>19 drafting that. I think it was drafted right</p> <p>20 before I came on to the board.</p> <p>21 Q. Did you have any involvement in the</p> <p>22 editorial process concerning that position</p> <p>23 statement in 2013?</p> <p>24 A. No.</p> <p>25 Q. Did you vote on it, whether it</p>
<p style="text-align: right;">Page 223</p> <p>1 and it's used by over I think it's 95 percent of</p> <p>2 AUGS members, and that there should be no</p> <p>3 limiting of that by any, you know, government</p> <p>4 body.</p> <p>5 Q. What's required to gain membership</p> <p>6 in that organization?</p> <p>7 A. Presently paying dues.</p> <p>8 Q. How much are the dues?</p> <p>9 A. I really don't remember. It's a</p> <p>10 couple hundred dollars a year.</p> <p>11 Q. Is there a board of directors for</p> <p>12 AUGS?</p> <p>13 A. There is.</p> <p>14 Q. What does it take to get on the</p> <p>15 board of directors?</p> <p>16 A. It just quoted you. How does that</p> <p>17 happen?</p> <p>18 Q. I don't know.</p> <p>19 MR. ROSENBLATT: We'll get Siri to</p> <p>20 testify.</p> <p>21 A. I'm sorry, what were you saying?</p> <p>22 Q. How do you get on the board of</p> <p>23 directors for AUGS?</p> <p>24 MR. ROSENBLATT: Object to form.</p> <p>25 A. It is usually an elected position.</p>	<p style="text-align: right;">Page 225</p> <p>1 should be issued by AUGS?</p> <p>2 A. No, I think it was right before I</p> <p>3 came on the board, I believe. I did not vote on</p> <p>4 that, but I would have voted for it.</p> <p>5 Q. Do you agree with the notion that</p> <p>6 when trying to determine the credibility of a</p> <p>7 statement one should consider the relationship</p> <p>8 between the one making the statement and the one</p> <p>9 benefitting from the statement?</p> <p>10 MR. ROSENBLATT: Object to form.</p> <p>11 A. Can you say that again?</p> <p>12 Q. Yes. Do you agree with the notion</p> <p>13 when trying to determine the credibility of a</p> <p>14 statement one should consider the relationship</p> <p>15 between the one making the statement and the one</p> <p>16 benefitting from the statement?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 A. Yeah, I think it's kind of a vague</p> <p>19 statement, but if you gave me a more specific</p> <p>20 example or maybe how it relates to what we're</p> <p>21 talking about, I'd be happy to answer that.</p> <p>22 Q. Do you agree that whether or not</p> <p>23 AUGS board members are receiving direct financial</p> <p>24 benefits from mesh manufacturers is a factor to</p> <p>25 consider when trying to determine the credibility</p>

<p style="text-align: right;">Page 226</p> <p>1 of an AUGS position statement?</p> <p>2 MR. ROSENBLATT: Object to form.</p> <p>3 Lack of foundation.</p> <p>4 A. I'll just say that I know the</p> <p>5 members of the board. I know the members of the</p> <p>6 board when this position statement came out, and</p> <p>7 I completely believe in their integrity and their</p> <p>8 motivation, and their motivation and their only</p> <p>9 motivation is to protect their patients, and I do</p> <p>10 not believe that there was any influence and</p> <p>11 financial compensation when they came out with</p> <p>12 the position statement.</p> <p>13 MR. CRAWFORD: I'll object as</p> <p>14 non-responsive and move to strike.</p> <p>15 My question is a little bit more</p> <p>16 narrow and tailored. I'll ask it again.</p> <p>17 Do you agree that whether or not</p> <p>18 AUGS board members are receiving direct financial</p> <p>19 benefits from a mesh manufacturer is a factor to</p> <p>20 consider in determining the credibility of an</p> <p>21 AUGS position statement about the use of mesh?</p> <p>22 MR. ROSENBLATT: Object to form,</p> <p>23 asked and answered.</p> <p>24 A. So I'm going to say it again,</p> <p>25 that -- by the way, there are some board members,</p>	<p style="text-align: right;">Page 228</p> <p>1 promote synthetic mesh products?</p> <p>2 MR. ROSENBLATT: I object to the</p> <p>3 characterization.</p> <p>4 A. I've taught at professional</p> <p>5 education courses, you know, under the support of</p> <p>6 medical device manufacturers.</p> <p>7 Q. Have you ever been part of Boston</p> <p>8 Scientific's Healthcare Professional or also</p> <p>9 known as HCP program?</p> <p>10 A. If that's what it's called. I</p> <p>11 guess maybe I am not familiar with that term, but</p> <p>12 I have taught for Boston Scientific, yes.</p> <p>13 Q. As you sit here today, you don't</p> <p>14 know whether or not you've ever been involved in</p> <p>15 the Boston Scientific Corporation Healthcare</p> <p>16 Professional Program?</p> <p>17 A. I don't think I've ever heard it</p> <p>18 referred to as that, but if that's what I've been</p> <p>19 a part of, then I think the answer is yes. I</p> <p>20 don't deny it. I just don't know what it's</p> <p>21 called.</p> <p>22 Q. In 2009, did you receive a</p> <p>23 quarterly payment of \$10,000 each quarter from a</p> <p>24 synthetic mesh manufacturer for participation in</p> <p>25 a program where you would mentor other doctors or</p>
<p style="text-align: right;">Page 227</p> <p>1 including the president, the -- I assume it's</p> <p>2 called the vice president or the president elect.</p> <p>3 No. Whoever the next in line is. There are</p> <p>4 several of the executive board who are not</p> <p>5 permitted to have any potential conflicts of</p> <p>6 interest.</p> <p>7 There are others on the board,</p> <p>8 myself included at the time, but not during the</p> <p>9 position statement but while I was on the board,</p> <p>10 that were permitted to have potential conflicts</p> <p>11 of interest, but we had to declare those</p> <p>12 potential conflicts of interest. So as long as</p> <p>13 you declare those potential conflicts of interest</p> <p>14 and you have integrity as a person and a</p> <p>15 physician, then I have no problem with what the</p> <p>16 position statement would say.</p> <p>17 MR. CRAWFORD: I object as</p> <p>18 non-responsive and move to strike.</p> <p>19 Can you answer the question I just</p> <p>20 asked you with a yes-or-no answer or is that</p> <p>21 impossible?</p> <p>22 A. I think it's impossible.</p> <p>23 Q. Okay. Have you ever been involved</p> <p>24 in a program whereby you were paid by a synthetic</p> <p>25 mesh manufacturer to mentor other doctors or</p>	<p style="text-align: right;">Page 229</p> <p>1 promote synthetic mesh products?</p> <p>2 MR. ROSENBLATT: Object to the</p> <p>3 form, the characterization of promote.</p> <p>4 A. Right, but I'm also asking you are</p> <p>5 you suggesting that I was paid \$10,000 regardless</p> <p>6 of what I taught?</p> <p>7 Q. No, I have no idea what you were</p> <p>8 teaching. I'm just exploring this issue.</p> <p>9 A. Understood. So I don't recall that</p> <p>10 particular year, but any time I've done any</p> <p>11 teaching for any mesh manufacturer I've been paid</p> <p>12 for my services. I have never been paid like</p> <p>13 a -- what's the word I'm looking for. Like a</p> <p>14 retainer. I've never been paid as a retainer.</p> <p>15 I've been paid for my services.</p> <p>16 Q. Have you ever received set</p> <p>17 quarterly payments?</p> <p>18 A. No, never.</p> <p>19 Q. Is it true that during the years</p> <p>20 2011 and 2012, that being the years leading up to</p> <p>21 the release of the 2013 AUGS position statement,</p> <p>22 you were paid approximately \$100,000 by Boston</p> <p>23 Scientific Corporation for participation in their</p> <p>24 Healthcare Professionals Program?</p> <p>25 A. I don't have the exact figures, but</p>

<p style="text-align: right;">Page 230</p> <p>1 that is possible, but I think -- did you say</p> <p>2 leading up to the position statement?</p> <p>3 Q. I said in 2011, 2012. I'll ask it</p> <p>4 again.</p> <p>5 A. Yeah, please.</p> <p>6 Q. Is it true that during the years</p> <p>7 2011 and 2012 you were paid approximately</p> <p>8 \$100,000 by Boston Scientific Corporation for</p> <p>9 participation in their Healthcare Professionals</p> <p>10 Program?</p> <p>11 A. If that's what it's called. I did</p> <p>12 consulting work for Boston Scientific, and it's</p> <p>13 quite possible that that was the amount of money</p> <p>14 that I was paid.</p> <p>15 Q. You're just not sure if it was</p> <p>16 called the Healthcare Professionals Program?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 A. Correct.</p> <p>19 Q. Of the 13 board members who were on</p> <p>20 the AUGS board when the 2013 position statement</p> <p>21 was released, how many of them had received</p> <p>22 financial compensation from synthetic mesh</p> <p>23 manufacturers during the two years preceding the</p> <p>24 release of the statement?</p> <p>25 A. I have no idea.</p>	<p style="text-align: right;">Page 232</p> <p>1 had a potential conflict of interest that would</p> <p>2 affect any decisions, we were asked to abstain</p> <p>3 from those decisions.</p> <p>4 Q. Doctor, I appreciate your patience</p> <p>5 with me in coming out here to talk to us today.</p> <p>6 At this point in time I don't have any further</p> <p>7 questions for you. I pass the witness.</p> <p>8 MR. ROSENBLATT: I'll be very, very</p> <p>9 brief.</p> <p>10</p> <p>11 FURTHER EXAMINATION</p> <p>12 BY MR. ROSENBLATT:</p> <p>13 Q. Doctor, we were just talking about</p> <p>14 AUGS position statement. I want to hand you --</p> <p>15 what are we on?</p> <p>16 MR. CRAWFORD: 21, I think.</p> <p>17 (Whereupon, Deposition Exhibit 21,</p> <p>18 AUGS position statement,</p> <p>19 was marked for identification.)</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. I'm going to hand you what's been</p> <p>22 marked as Exhibit 21. If you could take a second</p> <p>23 and flip through that.</p> <p>24 A. Mm-hmm.</p> <p>25 Q. Now, Doctor, do you see any</p>
<p style="text-align: right;">Page 231</p> <p>1 Q. Being a former AUGS board member,</p> <p>2 is that information you would expect to be kept</p> <p>3 in the regular course of business activity within</p> <p>4 the AUGS organization?</p> <p>5 A. So I guess I missed that point.</p> <p>6 Being an AUGS member, what was the question?</p> <p>7 Q. Being a former AUGS board member,</p> <p>8 do you believe that the information I just asked</p> <p>9 you about is information that would be kept in</p> <p>10 the regular course of business activity within</p> <p>11 the AUGS organization?</p> <p>12 A. Yes.</p> <p>13 MR. ROSENBLATT: Object to form.</p> <p>14 A. But let me just state that again</p> <p>15 there is I believe it's called the executive</p> <p>16 board that are not permitted to have any</p> <p>17 potential conflicts of interest, but any</p> <p>18 conflicts of interest, potential conflicts of</p> <p>19 interest of the other board members is declared</p> <p>20 and is publicly available.</p> <p>21 Q. How is it declared and where is it</p> <p>22 made publicly available?</p> <p>23 A. I don't know. All I know is that</p> <p>24 at every board meeting we were required to list</p> <p>25 any potential conflicts of interest, and if we</p>	<p style="text-align: right;">Page 233</p> <p>1 highlighting on this document?</p> <p>2 A. No, I do not.</p> <p>3 Q. Good. I will represent to you this</p> <p>4 is my only copy, but to spare counsel another set</p> <p>5 of questioning, I will not highlight anything.</p> <p>6 Was this position statement</p> <p>7 initially published in January of 2014 and then</p> <p>8 updated in June of 2016?</p> <p>9 MR. CRAWFORD: Objection to form.</p> <p>10 A. It was.</p> <p>11 Q. And was this position statement</p> <p>12 limited to the support of AUGS?</p> <p>13 A. No.</p> <p>14 Q. And if you could just describe the</p> <p>15 organizations that joined in showing their</p> <p>16 support for the AUGS/SUFU position statement?</p> <p>17 A. Right. And just so I know is this</p> <p>18 the one from 2000 -- this is the one from 2016?</p> <p>19 Q. Correct.</p> <p>20 A. Yeah. So there were other</p> <p>21 organizations that supported this, including the</p> <p>22 AAGL, the American Association of Gynecologic</p> <p>23 Laparoscopists, the American College of</p> <p>24 Obstetrics and Gynecologists, the National</p> <p>25 Association for Continence, and the Society of</p>

<p style="text-align: right;">Page 234</p> <p>1 Gynecologic Surgeons, as well as the Women's 2 Health Foundation.</p> <p>3 Q. So, Doctor, it would be fair to say 4 that the support for the AUGS/SUFU position 5 statement on midurethral slings is not limited to 6 professional societies but also patient support 7 groups such as the NAFC and the WHF?</p> <p>8 MR. CRAWFORD: Objection to form.</p> <p>9 A. That is correct.</p> <p>10 Q. And, Doctor, is this position 11 statement something that you would have received 12 on your own? Strike that.</p> <p>13 Doctor, is this position statement 14 something that you were made aware of directly 15 through AUGS?</p> <p>16 A. Yes.</p> <p>17 Q. Is this also something that was 18 provided to you by Butler Snow?</p> <p>19 A. Yes.</p> <p>20 Q. And so although it was provided to 21 you from Butler Snow, that was not in fact the 22 first time you had seen that document?</p> <p>23 A. That is correct.</p> <p>24 Q. And the same would be true for a 25 significant amount of medical literature that</p>	<p style="text-align: right;">Page 236</p> <p>1 things along today since counsel asked you to 2 find those during a break; is that correct?</p> <p>3 MR. CRAWFORD: Objection to form.</p> <p>4 A. That is correct. I mean, we have, 5 you know, one, two, three, four, I believe it's 6 five, yeah, banker's boxes of documents, and just 7 to expedite things, I asked you to print these 8 out. But these are articles that are in here 9 that I've highlighted either here or on my 10 computer.</p> <p>11 Q. And counsel asked you questions 12 about your experience teaching for various 13 manufacturers. Do you recall those questions?</p> <p>14 A. Yes.</p> <p>15 Q. And in his questions, he used the 16 word promote their products. What is your 17 interpretation of whether or not you were or 18 strike that.</p> <p>19 What is your understanding of 20 whether or not you were promoting products for 21 these manufacturers?</p> <p>22 MR. CRAWFORD: Objection, form.</p> <p>23 A. Yeah, so that's never been my goal, 24 is to promote a product for a company. My goal 25 is to share my experience with others. And you</p>
<p style="text-align: right;">Page 235</p> <p>1 we've discussed?</p> <p>2 A. That is correct.</p> <p>3 Q. And counsel asked you about some of 4 the studies that we looked at earlier where we 5 quickly went through and there was some 6 highlighting on those studies. Do you remember 7 those?</p> <p>8 A. Yes.</p> <p>9 Q. Had you reviewed those studies 10 prior to today's deposition?</p> <p>11 A. Yes.</p> <p>12 Q. And when counsel suggested that you 13 were just reading the highlights, would it be 14 fair to say that -- well, strike that.</p> <p>15 Would it be fair to say that 16 counsel asked you to provide some of the 17 documents and literature that you had discussed 18 with him earlier today?</p> <p>19 A. Can you ask that again?</p> <p>20 Q. Would it be fair to say that you 21 provided literature in response to some of the 22 questions that counsel asked today?</p> <p>23 A. Yes.</p> <p>24 Q. And you in fact asked me to print 25 out some of those studies so that we could move</p>	<p style="text-align: right;">Page 237</p> <p>1 know, just to give you an example, when TVT came 2 out, you know, and I was first very skeptical of 3 it, and then when I started using it, I realized 4 what an incredible advantage it was compared to 5 what I had been using previously. The same was 6 true with TVT-O when that came out. But, you 7 know, just to give another example with the same 8 company, I think it was 2006 is when Ethicon 9 introduced TVT Secur which is a single incision 10 sling, and I wasn't so sure about it. The data 11 was not as compelling as it had been for the 12 other slings, and my center did a randomized 13 prospective trial comparing TVT-O, which is 14 something that we had been using for several 15 years and very happy with, with TVT Secur. This 16 was a study that was funded by Ethicon, and we 17 decided even before we started the study that we 18 would do an interim analysis, and based on the 19 interim analysis, we felt compelled to stop the 20 study because the results were so significantly 21 different between TVT-O and TVT Secur where we 22 were not satisfied with the results, and we 23 published those results.</p> <p>24 MR. CRAWFORD: Objection. 25 Non-responsive.</p>

<p style="text-align: right;">Page 238</p> <p>1 Q. Did Ethicon try to prohibit you</p> <p>2 from publishing the results of that study in any</p> <p>3 way?</p> <p>4 A. No, never.</p> <p>5 Q. Did Ethicon try to retract the</p> <p>6 funding from that statement because of the data</p> <p>7 that you presented?</p> <p>8 A. No, that was never ever even a</p> <p>9 question, and it was based on I believe our study</p> <p>10 and several other studies that were similar</p> <p>11 studies that Ethicon decided not to -- decided</p> <p>12 not to sell that product anymore.</p> <p>13 Q. And would that be an example of how</p> <p>14 a product with less mesh such as TVT Secur is not</p> <p>15 necessarily a better product than something that</p> <p>16 uses -- than a product that has more mesh such as</p> <p>17 TVT-O just based on the amount of mesh that's</p> <p>18 used?</p> <p>19 MR. CRAWFORD: Objection to form.</p> <p>20 A. That is correct.</p> <p>21 Q. And you were asked some questions</p> <p>22 about consulting agreements with Ethicon. Do you</p> <p>23 recall those questions?</p> <p>24 A. Yes.</p> <p>25 Q. The consulting agreements to my</p>	<p style="text-align: right;">Page 240</p> <p>1 medical students, residents and fellows. We</p> <p>2 started the fellowship in 1999. This is what I'm</p> <p>3 dedicated to in my career. I would only teach</p> <p>4 products that I felt that were worthy of being</p> <p>5 taught and that were excellent products, but my</p> <p>6 teaching is based on the medical literature, it's</p> <p>7 based on evidence-based medicine, and I'm very</p> <p>8 comfortable with that.</p> <p>9 Q. And so the fact that Dr. Rosenzweig</p> <p>10 has testified that he has been paid by</p> <p>11 plaintiffs' counsel more than a million dollars</p> <p>12 in the pelvic mesh litigation, that alone would</p> <p>13 not in itself in your opinion automatically</p> <p>14 discount his opinions solely based on the</p> <p>15 millions of dollars he's been paid by plaintiffs'</p> <p>16 counsel --</p> <p>17 MR. CRAWFORD: Objection to form.</p> <p>18 Q. -- is that fair?</p> <p>19 A. I think it's a fair statement.</p> <p>20 Q. All right. Would you agree or</p> <p>21 disagree that there is a difference between</p> <p>22 actual bias and a potential for a conflict of</p> <p>23 interest?</p> <p>24 A. Yes.</p> <p>25 Q. You would agree?</p>
<p style="text-align: right;">Page 239</p> <p>1 understanding would list a maximum amount; is</p> <p>2 that consistent with your understanding?</p> <p>3 MR. CRAWFORD: Objection to form.</p> <p>4 A. Yeah, I do remember that.</p> <p>5 Q. So would it be fair to say that the</p> <p>6 amount listed on the consulting agreement is not</p> <p>7 necessarily an accurate portrayal of what you</p> <p>8 were actually paid for any given year?</p> <p>9 A. That is correct.</p> <p>10 Q. You were asked some questions about</p> <p>11 how much you're being paid here today and how</p> <p>12 much you've been paid over the time you were</p> <p>13 teaching Ethicon professional education.</p> <p>14 Do you think that payments you've</p> <p>15 received from industry for teaching on the safe</p> <p>16 and efficacious use of products has in any way</p> <p>17 inhibited your ability to provide a fair and</p> <p>18 balanced review of the medical literature</p> <p>19 regarding the products at issue?</p> <p>20 MR. CRAWFORD: Objection to form.</p> <p>21 A. So, you know, since I started in</p> <p>22 practice 21 years ago, I've always been</p> <p>23 committed. My primary interest is helping women</p> <p>24 and teaching surgeons. I mean, that's what I've</p> <p>25 been dedicated to being at Harvard, having</p>	<p style="text-align: right;">Page 241</p> <p>1 A. I would agree.</p> <p>2 Q. I appreciate your time, Doctor. No</p> <p>3 further questions.</p> <p>4 MR. CRAWFORD: I have nothing</p> <p>5 further. Thank you very much.</p> <p>6 (Deposition concluded at 3:37 p.m.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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1 C E R T I F I C A T E

2 I, Maryellen Coughlin, RPR/CRR and

3 notary public in the Commonwealth of

4 Massachusetts, do hereby certify that the

5 foregoing is a true and accurate transcript of

6 my stenographic notes of the deposition of

7 PETER L. ROSENBLATT, M.D., who appeared before

8 me, satisfactorily identified himself, and was

9 by me duly sworn, taken at the place and on the

10 date hereinbefore set forth.

11 I further certify that I am neither

12 attorney nor counsel for, nor related to or

13 employed by any of the parties to the action in

14 which this deposition was taken, and further

15 that I am not a relative or employee of any

16 attorney or counsel employed in this case, nor

17 am I financially interested in this action.

18 THE FOREGOING CERTIFICATION OF THIS

19 TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF

20 THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT

21 CONTROL AND/OR DIRECTION OF THE CERTIFYING

22 REPORTER.

23

24 MARYELLEN COUGHLIN, RPR/CRR

25

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1 I N S T R U C T I O N S T O W I T N E S S

2

3

4 Please read your deposition over

5 carefully and make any necessary corrections.

6 You should state the reason in the appropriate

7 space on the errata sheet for any corrections

8 that are made.

9 After doing so, please sign the

10 errata sheet and date it. It will be attached to

11 your deposition.

12 It is imperative that you return

13 the original errata sheet to the deposing

14 attorney with thirty (30) days of receipt of the

15 deposition transcript by you. If you fail to do

16 so, the deposition transcript may be deemed to be

17 accurate and may be used in court.

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2 E R R A T A

3 - - - - -

4 P A G E L I N E C H A N G E

5 _____

6 REASON: _____

7 _____

8 REASON: _____

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10 REASON: _____

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24 REASON: _____

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1 A C K N O W L E D G M E N T O F D E P O N E N T

2

3

4 I, _____, do

5 hereby certify that I have read the

6 foregoing pages, and that the same is

7 a correct transcription of the answers

8 given by me to the questions therein

9 propounded, except for the corrections or

10 changes in form or substance, if any,

11 noted in the attached Errata Sheet.

12

13

14 _____

15 PETER L. ROSENBLATT, M.D. DATE

16

17

18 Subscribed and sworn

19 to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____

22 _____

23 Notary Public

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25

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